
Research Initiative
on
Traditional Anti - Malarials
(RITAM)

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Research Initiatives on Traditional Anti-malarials (RITAM)

A collective multi institutional project to study clinically the efficacy of folk remedies and ayurvedic therapies for the treatment of malaria

Coordinated by

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PROJECT PROPOSAL

FOR RESEARCH INITIATIVE ON TRADITIONAL ANTI-MALARIALS (RITAM)

A collaborative project between two medical cultures

ABSTRACT

FRLHT, an NGO engaged in serious exploration of the contemporary relevance of Indian medical heritage, has taken initiative to develop a multi-institutional co-ordinated Research project on traditional anti-malarials.

The objectives of the project are two fold: first to document the traditional herbal practices as well as the Ayurvedic treatment packages and study the clinical effectiveness of these practices via. a population study preceded by pre-clinical studies; secondly to disseminate the effective remedies among the people.

The project will be implemented in 3 stages; 1st stage is to document the practices in select areas of the states of the North East, Bihar, Rajastan, Gujarat, Maharashtra, M.P. Orissa and Tamil Nadu. In the first stage an ayurvedic literature survey will also be made to find out the treatment packages* for malaria type fevers. The 2nd stage consists of laboratory tests and analysis of the treatment as well as clinical trials on short-listed remedies.

In the 3rd stage of the project it is proposed to disseminate effective herbal treatments against malaria, through education and other promotional activities.

In the final stage of the project we propose to "encourage" commercialisation & basic research on effective anti-malarial remedies.

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* Package here means the medicine and other supplementary advice on diet and other therapeutics practices in Ayurveda.

PROJECT PROPOSAL

FOR RESEARCH INITIATIVE ON TRADITIONAL ANTI-MALARIALS (RITAM)

a collaborative project between two medical cultures

1. **Title of the Project** : **Research Initiatives on Traditional Anti-malarials (RITAM)**

2. **Legal holder Name & Address** : **Foundation for Revitalization of Local Health Tradition (FRLHT) No.50, MSH Layout, Anandnagar, Bangalore**

Background of FRLHT and its involvement:

The Foundation of Revitalization of Local Health Traditions (FRLHT) started functioning as an independent non-Government organization in October, 1993. It has as its goal :

"To revitalise the traditional local health cultures by challenging them to demonstrate their contemporary relevance to serve the country's present and future health care needs."

To achieve this goal the organization has thus far initiated the following programs:

1. established a major medicinal plants conservation network consisting of 70 sites in the southern states of Kerala, Tamilnadu, Maharashtra and Andhra Pradesh.
2. developed a comprehensive computerized medicinal plants database on botanical, conservation, agriculture and trade aspects of medicinal plants.
3. Developed a comprehensive reference database of medicinal plants of India used in different codified systems – Ayurveda, Siddha, Tibetan & Unani.
4. Developed education materials on medicinal plants conservation and traditional knowledge, in the form of books, films, posters, maps etc.
5. Initiated a pilot multi-centric project for community based assessment of local health practices. (For further details please see appendix 11 - A New Awakening)

3. The Goal of RITAM

RITAM is a cross-cultural communication program across two medical cultures. It assumes a mutually respectful collaboration between modern medicine & traditional Indian systems of medicine.

The goal of the project is two fold: (i) **to assess on the parameters of modern & traditional medicine the effectiveness** of a set of antimalarial herbal drugs & treatment packages that have been traditionally used by different communities in different regions

including those that are advised in Ayurvedic texts, (ii) **promote the use** of positively assessed practices via community health & education programs

4. The Specific objectives

4. 1 To document plants and various folk herbal remedies which are traditionally used by local communities for prevention, treatment and environmental protection against malaria.

4. 2 To document treatment packages from Ayurvedic literature with respect to fevers that can be correlated to malaria.

4. 3 To screen and short-list folk herbal remedies and ayurvedic treatment packages through pre-clinical lab tests and other criteria based on traditional knowledge.

4. 4 To undertake a study of their efficacy on modern &traditional parameters through suitably designed population trails and using specially designed protocols for treatment and clinical monitoring.

4. 5 To promote the use of positively assessed remedies in rural and urban communities via community health and education programmes.

4. 6 To create a register for documenting local folk remedies and their sources and to ensure prior informed consent in line with Convention for Biological Diversity and the Indian bio-diversity act before local knowledge is used for research & commercial purposes.

4. 7 To encourage basic research on mode of drug action and also the development of an anti-malarial herbal drug for commercial use based on traditional remedies and with due protection and reward for Intellectual Property Rights of local communities and of the traditional medical systems.

5. Why this research (The Rationale)

5. 1 The resurgence or re-emergence of Malaria poses a major Public health problem in the world particularly in Africa and India. In 1976 it was estimated that there were about 6.4 million cases of malaria in India and present official estimates places the figure around 2 million (which seems to be a gross underestimate. the real figure may be 20 times higher) (1). States with relatively high malaria morbidity and mortality are Assam, Bihar, madhya Pradesh, Orissa, North-East and also Southern states. Incidence of Malaria in urban areas like Chennai is also rising (1).

5. 2 Until early 1800's treatment for malaria was the native perurian remedy of using the powdered bark of Cinchona tree (C.officinalis and C.succiruba). In 1815, the "active ingredients" were extracted from the bark viz. the alkaloids quinine and

cinchonine. The medical profession's romance with quinine started then & that continued despite availability of effective synthesised alternatives over the years. Only from the late 1920s were synthetic drugs also like chloroquine introduced as anti-malaria remedy although they never gained as much popularity as quinine (5). Today there are research groups who are proposing a revisiting of the powdered bark (or crude extract) of the cinchona tree in order to see if it overcomes problems of resistance.

The continued search for newer drugs also led to the discovery of the traditional Chinese drug "Qinghaosu" obtained from the herb Qinghao(Artemisia annua) with the active principle identified as artemesinin. This was earlier extensively used in crude form by traditional Chinese medicine for the treatment of malaria and was found to be very effective (4). Today artemesinin & other derivaties from the plant are in use but they are also expected to develop problems of resistance.

In 1998, the WHO initiated the "Roll Back Malaria" project with substantial financial investments in Malaria control, thus establishing malaria as one of its highest priorities (2). One of the greatest challenges facing malaria control world-wide is the spread and intensification of parasite resistance to anti-malarial drugs. All the four leading front-line drugs, chloroquine, sulphur-doxine-pyrimethamine, Mefloquine and Artesimine are facing problems of resistance and this has led to increasing difficulties in the development of anti-malarial drug policies and disease management. Resistance of P.falcipram to chloroquine has developed in all malaria-endemic countries. Resistance to sulfadoxine-pyrimethamine is widespread in South East Asia including India and Mefloquine resistance is now common in Thailand, Combodia and Myanmar. Parasite sensitivity to quinine is also declining in South East Asia (including parts of India) (3). In the last decade chloroquine resistant P.vivax strains have also been detected in increasing numbers in Indonesia and India, and this requires monitoring and liquidation of the emerging focii (3). Thus the management of malaria by western bio-medical strategy has evident problems and scientists are reconciled to the need to discover a new drug every five years because of the development of resistance.

There has been a dearth of studies on the role of Traditional Systems of Medicine (TSM) world wide in prevention and treatment of malaria. While several herbs such as chiraita and others have been mentioned in Classical Indian Texts and dozens of others are used locally by tribal groups (1), no systematic studies have been carried out to test their efficacy. Studies on plants to tackle the different aspects in Malaria control such as insect repellant plants (eg.Neem), prophylactic fever mixtures and prophylactic diet changes have also yet to receive sufficient attention

More than 60-70% of the population in India reside in rural areas for whom the first contact is with folk healers & practitioners of TSM. This alone is a good reason to explore these alternatives as an affordable, accessible and relevant health care (stress of primary health care) (6).

5.5 The Central Council for Research in Ayurveda and Sidda (CCRAS) in the seventees did study and recommend one combination of herbs for malaria viz - "Ayus – 64" (now commercially available as Chirakin) but the efficacy of the drug has not been to the expected level The Unani Council (CCRUM) has also recently proposed a herbal anti-malarial but data on its efficacy is awaited These two attempts have certainly not exhausted the potential of Traditional Systems of Medicine (TSM) or of the folk traditions in the country. They represent the tip of the iceberg or the beginning of the search for traditional herbal remedies The mode of action of traditional remedies is likely to be of tremendous value because they may show new strategies & pathway to deal with malaria or may also provide herbal drugs that can be used in combination with conventional remedies that otherwise face resistance problems.

5.6 There is therefore, definitely the need to urgently carry out clinical studies to scientifically evaluate the efficacy of herbal remedies in prevention and treatment of malaria (4) There is a need to evaluate therapeutic claims of such drugs which could be adopted easily for wider public use (1). This was also identified as an important policy recommendation by the Malaria Expert Committee group set up by VHAI (1). Refer recommendations in box. In A national roll back malaria strategy there is no need to only look for a single commercially viable magic bullet that can be universally applied. Local resource based decentralised solutions also have a great deal of relevance, even if they are only feasible for local use.

Box 1 – Recommendation of VHAI Expert Committee 1998

ASSESSMENT OF ROLE OF ISM

- A concerted effort be made to involve the practitioners. systems and councils of all health traditions in the country to understand and tackle the malaria problem.
- An interactive dialogue and research be initiated to build links between the framework of fever in all systems with malaria and to evolve suitable therapeutic strategies.
- Efforts be made to study and strengthen local health traditions and healing practice that may be helpful in malaria especially in areas of epidemics. A scheme may also be made to document and evaluate these local traditional health practices in different regions.
- Regular assessment and research of herbals that have antimalarial potential be taken by national drug research laboratories with clinical trails.
- An expert panel of physicians and scholars can be formed for timely evaluation and consultation in special areas.

WHO has a special programme for Research and training in Tropical Diseases (TDR) (six selected tropical diseases including malaria). In a recent meeting in August 2000 TDR has shown willingness to explore if traditional and folklore medicine might offer some solutions for malaria control, which are cheap and easily available to the local people. However the need for clinical validation of such traditional herbal therapies cannot be over emphasized (4).

This Research initiative has two distinct potentials. First, to establish clinically through multi-centric trials whether or not a set of folk practices as well as the treatment package of Ayurveda is effective in healing malaria patients. Second, to establish the mode of action of the same. The scope of the RITAM project is limited to the first aspect. As for the second aspect of basic research to establish the mode of action and commercial promotion of the proven herbal drugs, RITAM will only take steps to encourage interested agencies to initiate action in these directions.

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2. World Health Organisation (June 2000). Implementation of Collaborative Activities on Roll Back Malaria in the South-East Asia Region.
3. World Health Organisation (2000) WHO Expert Committee on Malaria WHO Technical Report Series No.892. Geneva.
4. World Health Organisation (1978) The promotion and development of traditional medicine. WHO Technical Report Series No. 622, Geneva.
5. Muraleedharan V.R. (1999) Quinine and the incurable Malaria : India C. 1900 – 1930. Medical History (Accepted for publication)
6. Gaitonde R (1998) An Exploration of Health and Healing (with special reference to some alternative systems of health care. Accepted for publication)

6. Ethical Issues

In the proposed RITAM program all the ethical guidelines on bio-medical research involving human subjects of Indian Council of Medical Research and the provisionn relating to benefit sharing with local communities of the Convention of Biological Diversity (CBD) will be followed.

7. Criteria for selection of Field sites for population trials

The first & second criteria below are necessary conditions for selection of a field site.

7. 1 Significant incidence of malaria in the selected location i.e. the field site should correspond to the districts of high malaria incidence identified by NMEP (National malaria eradication program)

7. 2 Competent community health NGO's active at the select locations who was willing to participate in RITAM.

7. 3 Prevalence of traditional health practices in the local communities.

8. Expected Outcomes

8. 1 Identification of 6-9 antimalarial folk drugs including ayurvedic treatment packages that are traditionally used by various communities and/or are advised in Ayurvedic literature.

8. 2 Results of pre-clinical studies on the selected remedies.

8. 3 Data on clinical efficacy of selected folk herbal remedies and treatment packages drawn from Ayurveda, on modern and traditional parameters based on limited population trials.

8. 4 Development of an education/communication strategy to promote community use of positively assessed antimalarial herbal drugs & treatments

9. Strategy

9. 1 To document the anti malarial herbal remedies used by different communities with the help of reputed NGOs as well as select the Ayurvedic treatment packages for Malaria type of fevers through survey of Ayurvedic literature. Every NGO will have a qualified Ayurvedic practitioner in the team. (see Appendix 1 –addresses and details about participating NGOs and MoUs signed by them)

9. 2 Carry out preclinical and toxicity tests on selected herbal remedies via reputed research institutions like National Institute of Immunology, Indian Institute of Science and Sir Dorabji Tata centre for Tropical Disease Research, Bangalore etc.

9. 3 Implement population trials in collaboration with same NGOs who were involved in field survey.(See Appendix 2 letters of agreement from the labs)

9. 4 Promote positively assessed herbal remedies/treatment packages via suitably designed community health and education programs.

10. Implementation stage 1

The first stage of implimentation consists of five task: (i) Trainings to equip the field personnel for field survey and clinical trial (ii) Field survey (iii) Ayurvedic literature survey (iv) Laboratory tests/ analysis (v) selection of the remedies for clinical trial.

10.1 Trainings

The following trainings have to be conducted to equip the field personnel

- Training for field survey for the field workers and documentation incharge
- Training for lab technitians
- Training for clinical trial
- A short training may be required on the administration of the medicine and the necessary instructions after each centre is provided with the drug to be tried out in that particular region.

10.2 Field survey (ethno graphic)

The participating NGOs will document the local herbal medicines used by people in selected rural areas. They will;

- select definite area (villages/talukas)
- collect data on the local incidence of Malaria
- identify the traditional medical practitioners
- collect information about their practices both preventive and curative for malaria (via. methodologies like PRA, informal discussion)
- collect specimens of plants and prepare herbarium records of the plants used by the community
- The plant & other local remedies will also be sent to the RITAM Secretariat for toxicity and pre-clinical tests.

(see Appendix 3 proforma for field survey)
(see Appendix 4 proforma for ethno-medical survey)
(see Appendix 5 documentation sheet for field survey)

Traditional ISM literature search

Although there is no such term as `Malaria' in Ayurvedic literature the traditional Ayurvedic literature contains package treatments for fevers which have similar symptom complex as malaria. These treatment packages for management of Malaria type of fevers will be intelligently selected in order to establish their effectiveness through clinical trials (see Appendix 6 for note on methodology of Ayurvedic literature search)

Laboratory tests/ analysis

10.4.1 Lab test for standardisation of formulations

The local herbal remedies will be standardised by research team at RITAM secretariat, Bangalore before being sent for pre-clinical tests.

- The preparation of formulation from authenticated raw drugs will be done either at FRLHT or by NGO according to the folk advice or to Ayurvedic formulary.
- The formulations(s) will be studied for physico-chemical characters as well as microbial quality.
- A batch preparation of the formulation for what will be done to accommodate qualities required for entire testing protocol. This is to avoid batch to batch variation in the tested material.
- The preparation will be tested for the above mentioned quality parameters
- Suitable precaution will be taken by using codes for the herbs in the whole process of research.

10.4.2 Pre-clinical In vitro and in vivo screening for paraciticidal effect.

Dr G Padmanabhan, Indian Institute of Science (IISc) and Dr Raghunandan Sir Dorabji Tata Trust (SDTT) centre for Tropical diseases have offered to do some of these studies and Dr. Antia of Foundation for Research and Community Health (FRCH) has also offered to do pre-clinical In vitro and In vivo tests

10.4.3 Immunomodulatory test

It is possible that many anti-malaraial plants currently being used do not have any direct paraciticidal effect. In the scientific Advisory Committee meeting organised on 5th August, at FRLHT, the scientists were of the opinion that if immunomodulatory effect of a plant is established and the plant has been widely used in community as an antimalarial drug, it could be taken for clinical trial.

Dr. Shakti Upadhyaya, National Institute of Immunology, New Delhi will be doing the immunomodulatory tests.

10.4.4 Toxicity test

The different plants selected from various regions will be subjected to rapid toxicity tests, if necessary, based on a WHO protocol.[The Scientific Advisory Committee meeting held on 5th August at FRLHT were of opinion that, if a treatment or a plant has traditionally being used, this need not be subjected to toxicity test. This is also mentioned in the guidelines of A ICMR. (See appendix 10 ethical guidelines)

Dr. Ranjit Roy Choudhury, National Institute of Immunology, New Delhi has agreed to do the toxicity tests. (see Appendix 7 for protocol for lab tests)

10.5 Listing out the drugs/ treatment packages and selection and approval of six to nine remedies by expert committee for population trail in the selected regions.

After subjecting the medicinal plants and remedies for toxicity and preclinical tests, and immunomodulatory factors an expert groups comprised of both SAC and Ethical Committee will select about 6-9 remedies for field clinical trial. The expert committee will also approve the treatment packages advised by Ayurveda for management of Malaria.

11. Implementation Stage II

11.1 Population trial/clinical trial and documentation (first season)

The health centres (NGOs) will inform the patients or their relatives about the objectives & rationale of RITAM. Their consent will be obtained for using the drugs and the treatment packages. Compliance agreements will be signed either by the patient or a legally acceptable relative.
Criteria for inclusion & exclusion of patients in the trial will be based on standard guidelines. (see Appendix 8 protocol for clinical trial)

The proposed drug will be administered based on the treatment protocols developed by RITAM program (see Appendix 9 documentation sheet for clinical trial)

The improvements or changes in the patient will be observed, examined and recorded, as per the case sheet protocol on modern & traditional medicine parameters.

We expect to treat about 100 patients in each region (field centre) with the herbal remedy/treatment packages

At the end of the first season, the reports from different centres will be analysed and consolidated. The SAC will study the report and give their opinion on any shortcomings. In 2nd year the trial will be continued as recommended by the SAC

11. 2 Compilation and analysis of clinical trial and interim report.

An interim report will be prepared at the end of the first season

11. 3 Midterm review of results of population trial by SAC, Ethical committee NGOs involved and RITAM Secretariat team.

11. 4 Repeat population trial in 2nd season , as per SAC advice

11. 5 The final report at the end of second season

12. Implementation Stage III

12.1 Dissemination of the effective remedy/ treatment in the community

The remedies which are established to be effective will be promoted in the community. The NGOs will use different promotional methods to disseminate their use.

13. Implementation Stage IV

13. 1 Patenting and sharing of benefit: Patenting of positively assessed remedies may be undertaken if found to be feasible and potentially profitable.

13. 2 Commercial concerns will be encouraged to "work" the patent and share benefits on fair terms based on Convention for Biological Diversity for equitable sharing of benefits.

13.3 Basic research centres will be encouraged to work on `mode of action' of effective remedies found to be effective through clinical trial.

14. Action Plan

14.1 Preparatory stage

Sl No.	The Task	Person(s) Responsible	Time frame	Expected Outcome
14.1.1	Identification of NGO partners and signing the MoU	RITAM Secretariat	By August end	NGOs identified
14.1.2	Planning Meeting with the NGOs	Done	29th July 2000	NGOs accepted the program
14.1.3	Budget proposal and action plan from NGOs	Fr. Meloo	By Sept 15th	Done
14.1.4	Prepare the draft proformas for:			
	a. field survey (ethno medical)	As per minutes	Sept 10th	Done
	b. malaria incidence in project area	Krishnan to look at blue book of NAP	Sept 10th	Done
	c. clinical trials	As per minutes	Sept 10th	Done
14.1.5	Scientific Advisory Committee meeting to firm up RITAM strategy	Done	5th August 2000	SAC endorsed the proposal
14.1.6	Ayurvedic expert committee meeting to approve methodology to correlate ayurvedic disease entities with Malaria	Dr. Damle	20rd August '00	Committee gave suggestions on mode of procedure for literature survey
14.1.7	Area selection by NGOs (Village/Taluk/District)	NGO's	On going	To be completed by October '2000end
14.1.8	Preparing the project proposal	Fr. Melu , Mr. Darshan, Dr. Damle, Dr. Krishnan, Dr. Bharath Shah	15th September	done
14.1.9	Send the Project proposal to the donor agencies	RITAM Secretariat (Fr. Meloo)	20th Sept	

15. Action plan (Stage I)

15.1 Trainings, Field survey, Ayurvedic literature search and selection and approval for clinical trial

Sl No.	Activity	Person(s) Responsible	Time frame	Expected Outcome
15.1.1	Prepare training modules on treatment protocols & case sheet documentation for the use the selected remedies/ treatment packages	RITAM ISM team Dr. Damle Dr. Unnikr-ishnan	Feb 2001	Training module protocol & proforma for case study a is ready
15.1.2	Prepare training modules for the lab technicians	CHC	Feb 2001	Module for lab technicians ready
15.1.3	Organize and conduct the training for lab technicians	CHC	March 2001	Lab technicians equipped for field trials
15.1.4	Conduct training for clinical trials	RITAM ISM team+SEARCH Gudcheroli	March	Field staff equipped for clinical trial
15.1.5	Prepare 'consent' form to be signed by the patients	Bharat Shah	20th Jan 2001	Consent form ready
15.1.6	Prepare training modules for the ISM practitioners and others involved in ethno-medical survey	Fr. Meloo	Jan 5-15 2001	Training modules for ISM practitioners & field staff ready.
15.1.7	Conduct trainings for field staff involved in the project	Fr. Meloo	Jan 3rd to 4th week 2001	Field staff equipped for program

15.2 Field survey

Sl No	The Task	Person(s) Responsible	Time frame	Expected Outcome
15.2.1	Conduct field survey (ethno-medical) in each area	NGO	Feb-March 2001	Folk practices against malaria from the project area are documented
15.2.2	Collect the plants used for Anti malaria for herbarium specimen and for lab test	NGO	March 2001 (before summer)	Plants available for test

15.3 Ayurvedic literature search

Sl. No.	The Task	Person(s) Responsible	Time frame	Expected Outcome
15.3.1	Conduct search in Ayurvedic literature for treatment packages for Malaria type of fevers	RITAM ISM team (Dr. Damle) Dr. Unnikrishnan Dr. Venu	Jan 1-15 2001	Ayurvedic packages selected
15.3.2	Standardise treatment package before sending for pre-clinical tests.	FRLHT Lab Padma	Feb 2001	
15.3.3	Lab tests for pre-clinical screening	MoU labs	March 2001	
15.3.4	Toxicity tests if necessary	MoU labs	March 2001	

15.4 Laboratory analysis

Sl No	The Task	Person(s) Responsible	Time frame	Expected Outcome
15 4 1	Standardise herbal remedy before sending for pre-clinical test	FRLHT, Dr. Padma	April 2001	Treatments standardised
15 4.2	Lab test for pre-clinical studies	Labs with whom MoU has been signed by RITAM	April 2001	Toxicity of the plant if any identified
15 4.3	Lab test for toxicity if necessary	-do-	April 2001	

15.5 Selection and Approval by SAC and Ethical Committee

Sl. No.	The Task	Person(s) Responsible	Time frame	Expected Outcome
15. 5.1	List the treatment packages and herbal remedies for SAC approval	SAC - CHC	May 2001	Ayurvedic treatment for field trial selected
15.5.2	SAC study the listed remedies and select 6-9 herbal and/or treatment packages for clinical trial	SAC (RITAM Sec)	May 3rd week 2001	Medicinal for clinical trial for each region is selected
15 5 3	Ethical committee review the pre-clinical process and approve the medicines for pre-clinical trial	Ethical Committee (RITAM Sec.)	May 4th week 2001	Medicinal for clinical trial for each region is approved

16. Action Plan Stage II

16.1 Clinical trial/documentation

Sl. No.	Activity	Person(s) Responsible	Time frame	Expected Outcome
16.1.1	Preparation of medicine and supply of standardised herbal remedy/treatment package to the centres	RITAM Secretariat	May- June 2001	Medicine is available at the centres in each region
16.1.2	Accept patients as per inclusion & exclusion criteria, get informed consent and compliance agreement signed	NGO	June-Sept 2001	Patients prepared for treatment with new medicine
16.1.3	Administer to the patient the standardised drugs/treatment package as per the treatment protocol	NGO	June-Sept 2001	Clinical trial being done
16 1.4	Observe the patients and note down the developments as per documentation sheets both for modern medicine and Ayurveda	NGO	June-Sept 2001	Report of each patient ready

16.2 Data analysis and report

Sl. No.	Activity	Person(s) Responsible	Time frame	Expected Outcome
16.2.1	Analyse the data and prepare preliminary report and send to the RITAM Secretariat	NGO	Oct last week 2001 (at the end of 1st phase)	All the reports from the regions are gathered in the RITAM secretariat
16.2.2	RITAM secretariat will review the reports, combine them and prepare interim report for SAC AND Ethical Committee	RITAM Fr. Meloo	Oct 2001	Report is ready for scientific committee to study
16.2.3	The scientific advisory committee study the data	SAC – CHC	Nov 2001	Approval/opinion of the effectiveness of the treatment by the SAC is obtained
16.2.4	Midterm review of the project	SAC - CHC Ethical Committee & NGOs	Dec 2001	Project is evaluated

16.3 Repetition of clinical trial in the second season

Sl. No.	Activity	Person(s) Responsible	Time frame	Expected Outcome
16.3.1	Continue/modify the clinical trial process and documentation for a 2nd season, as suggested by the committee after midterm review.	NGO	June to Sep 2002	The scientific validation of the treatments is confirmed through another period of trial
16.3.2	SAC & Ethical review committee meeting after 2nd season.	SAC – CHC	Oct 2002	SAC and ethical committee approve the treatments tried out
16.3.3	Data analysis	RITAM (Fr. Meloo)	Oct-Nov 2002	Data is compiled and studied
16.3.4	Write the final report	Fr. Meloo	Dec 2002	Report ready
16.3.5	Publication of the report	Fr. Meloo	Jan 2003	Research outcome is published
16.3.6	A meeting of all involved in RITAM	RITAM Sec.	Jan 2003	Consensus on the strategy of further promotion positively assessed antimalarials

17. Action Plan Stage III

17.1 Promotion of the proved drug among the communities

Sl. No.	Activity	Person(s) Responsible	Time frame	Expected Outcome
17.1.1	Prepare promotional strategy	NGO/RITAM Sect) Fr. Meloo	2003 Jan	Strategy for promotion ready
17.1.2	Implement strategy in field areas to promote the herbal medicine/treatment package via. community health & peoples organizations etc.	NGO	Jan – Dec 2003	Malarial remedies are promoted among the people

18. Action Plan Stage IV

18.1 Patenting and sharing the benefit of communities

Sl. No.	Activity	Person(s) Responsible	Time frame	Expected Outcome
18.1.1	Take steps to patent the herbal medicines if feasible	RITAM Sect/ Fr. Meloo/ NGO	Mar 2003	Agencies contacted
18.1.2	Encourage commercial agency to enter into fair Material Transfer Agreement and Information Transfer Agreement.	RITAM Sect/ Fr. Meloo/ NGO	Mar 2003	- Agreement signed with agencies - produce the medicine commercially
18.1.3	Encourage Research Institutes to take up `mode of action' studies	RITAM Sect/ Fr. Meloo/ NGO	Mar 2003	Proposal is made to a research institutes for further research on the mode of action

19. Monitoring and Evaluation System

The phase wise action plans with expected outcomes will be the indicators for monitoring and evaluation.

Names of Scientific Advisory Committee

1 Mr. Darshan Shankar Director, FRLHT., Bangalore (Convenor)
2 Dr Ranjit Roy Chaudhuri - Emeritus Professor National Institute of Immunology Chairman, ICMR Committee of Traditional Medicine
3. Dr. Shakti Upadhyay- Prof. of Immunology , NII, New Delhi
4. Dr. V.P. Sharma – Consultant Roll Back Malaria Program WHO SEARO New Delhi
5 Vd. I. Sanjeeva Rao, Chairman, Ayurvedic Pharmacopia Committee, Government of India, New Delhi
6. Dr. G. Padmanabhan -Former Director, II Sc., Bangalore
7. Dr. Ravi Narayan – Community Health Advisor, CHC, Bangalore
8. Lt. Gen. Dr. Raghunath- Director Sir Dorabji Tata Trust, Centre for Tropical Division IISc, Bangalore
9. Vd. Ramesh Warrier - Managing Director, Arya Vaidya Nilayam, Madurai
10. Vd. Dr. Hrishikesh Damle – Ayurvedic Practitioner , Karnataka
11 A.V. Balasubramanian – Director, Centre for Indian Knowledge Systems, Chennai
12. Dr. Abhay Bang – Director SEARCH, Gadichiroli, Maharashtra

Staff of RITAM Secretariat

1.	Dr. Bharat Shah	(part time)
2.	Dr. Padma Venkat	(part time)
3.	Vd. Unni Krishnan	(part time)
4.	Fr. Meloo, S.J.	(full time)
5.	Dr. S.K. Krishnan	(part time)
6.	Dr. Venugopal	(part time)
7.	Consultants	(part time)
+	Administrative staff	(full time)

Consultants

1. Dr. C.M. Francis – F ounder –Director, Sree Chitra Tirunal Centre, Trivandurm
Former Dean of St. Johns Medical college, Bangalore

2. Dr. Joy David - Research consultant, Dept. of Pharmacology, St. Johns medical college, Bangalore

NGO Partners:

1. Trust for Reaching the Unreached (TRU) - Gujarat
2. Catholic Health Association Of Bihar (CHABI) - Bihar
3. Catholic Health Association of Orissa (OCHA) - Orissa
4. Society for Developmental and Rural Action (SODARA) – A P
5. Centre for Indian Knowledge System (CIKS) – T.N.
6. SAMANVYA Centre for awareness for Holistic Health - Gujarat
7. Centre for Health Edu. Trg and Nutrition Awareness (CHETANA)- Gujarat
8. PRAYAS - Rajasthan
9. SEARCH - Maharashtra
10. SAMBHAV M.P.
11. NECHA (Thru. Dr. Sunil Kaul) -North East

BUDGET ABSTRACT

SL.NO.	BUDGET ABSTRACT FOR RITAM	AMOUNT
1	For NGO for Phasel,II,III @ Rs. 18,93,250 x 11 NGOs (see statement 1 for details)	20825750
2	RITAM Secretariat Budget	
	a) For PHASE I (see statement 2a for details)	
	- Module preparation &Trainings	470000
	- Ayurvedic literature survey	60,000
	- Standardization of herbal and ayurvedic treatment	90,000
	- Meetings	
	* SAC meeting	200,000
	* Review meeting	200,000
	Total for PHASE I (RITAM - Sec)	**1020000**
	b) For PHASE II (see statement 2b for details)	
	* Data analysis and interim report	150000
	* Meeting (3)	600000
	* Final report and publication	250000
	Total of PHASE II	**1000000**
	c) Total for PHASE III RITAM Secretariat (see statement 2c for details)	300000
	d) Total Admin. Expenses (Phase I,II,III) of RITAM Secretariat (see statement 2d for details) & Consultancies	4044200
3	Total for lab tests (see statement 3 for details)	2400000
4	Miscellaneous & Contingency: 5% of the total	1479498
	GRAND TOTAL	**31069448**

Statement I

BUDGET FOR NGO

	PARTICULARS	Year I (2001)	Year II (2002)	Year III (200	Total
1	One ISM Doctor (part time) @ Rs 6000/month for 2 years	72,000	79,200		1 51 200
2	Two field workers @ Rs.5000/pm for 3 years	1,20,000	1,32,000	1,35,000	3 87 000
3	One person for documentation @ Rs.5000 (part time) for 2 years	60,000	66,000		1,26,000
4	One lab technition (part time) @Rs.4000 for 2 years	48,000	52,000		1,00,800
5	Expenses for QBC+ lab accessories	1,50,000			1 50 000
6	Expenses for 50 blood smear test @ Rs 50/slide for 2 years	2,500	2,750		5 250
7	Preparation of medicines for 50 patients each year for 2 years	50,000	55,000		1 05 000
8	Administration of medicine observation and documentation of 100 patients in 2 years	50,000	55,000		1 05 000
9	Travel for 3 years	40,000	44,000	48,400	1,32,400
10	Office administration for 3 years (part time?)	50,000	55,000	60,500	1 65 500
11	Stationary and communications for 3 years	50,000	55,000	60,500	1,65 500
12	Expenses for dissemination (Teaching materials training etc.)			3,00,000	3,00,000
	Total				18,93,250
	Total for 11 NGOs 18,93,250 X 11				2,08,25,750

B/L = boarding & lodging

Budget PHASE I for RITAM Secretariat
Field Survey Ayurvedic literature survey

SINo.	Item	Year I 2001 (6 months)	Total
1	Prepare modules for training for field survey	30000	
2	To conduct the training * TA/DA for Resource persons + participants * B/L for participants +resource persons * Honorarium for resource persons (@ Rs.4000 for 25 participants)	100000	130000
3	To prepare training modules, protocols documentation sheet for clinical trial	60000	60000
4	To prepare modules for lab technicians training	30000	30000
5	To conduct both trainings * TA/DA for resource persons * TA/DA for participants * Honorariumm for resource persons * Training materials * B/L	250000	250000
6	To collect plants from the field to RITAM secretariat	10000	10000
7	To standarsize H. remedies for pre clinical tests	50000	50000
	Ayurvedic treatment packages		
8	To conduct Ayurvedic lit. search	60000	60000
9	To standardise ayurvedic treatment package	20000	20000
10	Short listing of remedies for approval	10000	10000
11	SAC +Ethical Committee meeting for approval of the medicine for clinical trial	200000	200000
12	Review meeting with SAS, Ethical committee, NGOs and RITAM Secretariat	200000	200000
	Total		**1020000**

BUDGET FOR PHASE II FOR RITAM SEC Clinical Trial				
Sl.No.	Items	I Season	II season	Total
1	RITAM secretariat to process the records from all centres+Data analysis + interim report	100000		100000
2	SAC and ethical committee meeting at the end of 1st season to study the report	200000		200000
3	Repeat clinical trial for 2nd season (if suggested by SAC + ethical committee		NGO budget	
4	Collection & process of data of 2nd season		50,000	50000
5	SAC and ethical committee review meeting	200000		200000
6	Final data analysis, final report & publication of final repor	250000		250000
7	Final meeting with all involved in RITAM program at the end of the 2nd season **TOTAL FOR PHASE II**	200000		200000 1000000

B/L = boarding & lodging

COMMUNITY HEALTH CELL LIBRARY AND DOCUMENTATION UNIT
DIS-317

Statement 2(c)

RITAM SECRETARIAT BUDGET FOR PHASE II Promotion - Dessimination					
Sl.No.	Items	YEAR I	YEAR II	YEAR III	TOTAL
1	To prepare and facilitate promotional strategy by RITAM Secretariat			3,00,000	3,00,000

Statement 2(d)

RITAM Secretariat - administrative Expenses					
Sl.No.	Items	YEAR I	YEAR II	YEAR III	TOTAL
1	Salaries of RITAM (full time &part time staff)	240000	262000	288000	790000
2	Secretarial charges	120000	132000	145200	397200
3	Stationery	50000	55000	60500	165500
4	Communications	300000	330000	333000	963000
5	Travel	300000	330000	333000	963000
6	Consultants	200000	200000	200000	600000
7	Auditing	50000	55000	60500	165500
	Total Admin. Expenses				**4044200**

Statement 3

BUDGET FOR LABORATORY

Sl.No.	Item	Year I 2001 (6 months)	Total
1	Lab test for pre clinical trial @ Rs 1,00,000 per lab by 5 labs	500000	500000
2	Toxicity test (if needed) @ Rs.1,00,000 by 5 labs	500000	500000
3	Immuno modulatory factors - test	200000	200000
4	Lab test for pre clinical trial @ Rs.1,00,000 per lab by 5 labs	500000	500000
5	Lab test for pre clinical trial @ Rs.1,00,000 per lab by 5 labs	500000	500000
6	Immuno modulatory test of Ayurveda package	200000	200000
	Total		**2400000**

ADDRESS AND BRIEF DETAILS ABOUT THE PARTICIPATING NGOS

THRUST FOR REACHING THE UNREACHED (TRU)
210, Mangaladeep Complex, productivity Road, Alkapuri, Vadodara 390 005
Ph. (0265) 338117

The main trust of this organisation (founded in 1987) is to meet the Health Care needs of the neglected population of urban and rural India. The program focus on providing quality accessible health care. Now it has expanded its focus to include health education, preventive promotive outreach, supplementary school education and women's mobilization. TRU will be implementing the program in Godhara Dt. of Gujarat.

CATHOLIC HEALTH ASSOCIATION OF BIHAR (CHABI)
Ursuline compound campus, purlia Road, Ranchi-834 001, BIHAR.

It is the regional unit of the catholic health association of India. CHABI has about 250 institutions, as its members. Most of these are in very remote areas of Bihar. Besides providing health services mostly to the poor and the neglected, it promotes Community Health Programmes Organising and empowering people to take responsibility of their health. CHAB is now involved in an anti-malaria, Campaign programme in Daltongung district of Bihar.

CHABI will implement the project in Palamu Dt. and in one village (Satia) in Pakur Dist.

Catholic Health Association of Orissa (OCHA)

OCHA is the Orissa regional unit OF CHAI. Like any regional unit of CHAI. OCHA's main thrust is the promotion of community based health action. In 1996 –97 OCHA had launched A very successful malaria control programm in several districts of Orissa. Herbal medicines was widely used in this campaign. Most of its 215 member institutions (hospitals and dispensaries) as well as health workers in the villages do use herbal medicines against malaria.

OCHA will be implementing the program in Mayurbhang & Sambalpur Dt. of Orissa.

5. SODARA – Society for Developmental and Rural Action. SGT (St. Gabriels Trg Institute), UPPAL P.O. Hyderabad 500 039 Ph. (040) 7201017 Fax (040) 3322872

SODARA is a member of Catholic Health Association of India (CHAI). Its main trust is promotion of community health. Peoples' organisation is one of its main focus and through such peoples' organisation, it takes up programmes like watershed development. Its main area of operation is Nalgenda District of Andhra Pradesh.

SODARA will implement the program in Nalagonda Dt of A.P.

SAMANVYA Centre for awareness for Holistic Health, Vinoba Ashram, Gotri, Vadodara 390 021, Ph (0265) 343880, Fax (0265) 313463; Email:bharats@fnmail.com

This centre is looking at creative ways of integrating modern medicine i.e. Ayurveda and yoga. Work on holistic health is being led by Dr. B.Shah who is MD peadatrics &

SAMANVYA Centre for awareness for Holistic Health. Vinoba Ashram, Gotri Vadodara 390 021. Ph (0265) 343880, Fax (0265) 313463. Email bharats@fnmail com

This centre is looking at creative ways of integrating modern medicine i e Ayurveda and yoga Work on holistic health is being led by Dr. B Shah who is MD peadatrics & has spent a decade in rural health services. (Samanvya has yet to identify the districts)

Centre for Indian Knowledge System (CIKS) 30 Gandhi Mandapam road,
Kotturpuram, CHENNAI – 600 085 PH. 91-044-4471087, Fax 4471114
Email: info@ciks.org.

CIKS is engaged in looking at the contemporary relevance of Indian Knowledge Systems. It is based in Chennai. CIKS is doing pioneering work on organic agriculture based on Vrikshaayurveda. CIKS's thrurst areas are Agriculture & Health. CIKS has also authored several books in these areas.

CIKS's area of operation: the clinical trials will be in Madras city itself. The field survey however will be done in A Kancheepuram Dt. of T.N.

CHETANA (Centre for Health Education, Training and Nutrition Awareness) Leelavatibehen Lalbhais Bungalow, Civil Camp Road. Shahibaug. Ahemdabad 380 004. GUJERAT; Ph. (079) 2868856, 28666695

CHETANA an activity wing of Nehru Foundation. Ahemadabad is involved in womens welfare programmes, especially organising and empowering them with health skills Promotion of Herbal medicine is one of their main thrust besides other empowerment programmes.

For data collection, CHETANA will be involved in one Dt. in Rajasthan and one Dt. in Gujarat, as they have network of NGOs in these two states. Clinical trial will be done in the Ayurvedic college Ahmedabad, Gujarat.

Other partners:

Besides these seven NGOs who already signed the MOUs. The following NGOs from Rajastan. Maharashtra, Madhya Pradesh and North Eastern Region also have agreed to participate in the RITAM programme.

PRAYAS, B-8, Bapunagar, Senthi, Chittorgarh, 312035, Rajasthan;
Ph. 01472-43788 email: prayas@gpl.dot.net.in

SEARCH, Shodha Gram, P.O. & Dt. Gadchiroli 442 605, Maharashtra;
Ph. 07138 – 5407, Fax 07132 - 22403 email: search@satyam.net.in

NECHA - (Through Dr. Sunil Kaul) Catholic Health Association of North East
Ph. 0361 -221794 email: necha@gw1.vsnl.net.in

SAMBHAV, Indore

MOU

is is the agreement between RITAM Secretariat (FRLHT) and Samanvaya, Jatan Trust, dodara on this date of 28-08-00.

der mutual agreement THE NGO `Samanvaya' agrees be associated with RITAM c/o FRLHT to ry out the following works in the specified time.

The NGO shall carry out ethno-medical survey of his locality in the villages selected for the study.

The NGO shall collect the ethno-medical data within 90 days of commencement of RITAM program,

The NGO shall submit the data to secretariat in a specified format.

The NGO shall engage one qualified Traditional medicine practitioner for the population study, whose salary will be paid for by RITAM. (Will make our best try)

The NGO shall ensure access to a Lab with a qualified Lab technician experienced in Malaria Diagnosis.

The NGO shall document the clinical trial data on agreed formats and provide the data to secretariat every 30 days.

The NGO shall arrange for dispensing of the Standardised herbal remedies to the malaria patients of the locality for treatment & prevention of MALARIA.

The NGO shall participate in dissemination of positively assessed traditional practices in the locality.

The NGO will be entitled for a mutually agreed financial aid to support costs on RITAM.

The NGO will not transfer traditional information on remedies to any other commercial or research organization or individual and shall not publish any paper in a journal or Magazine without prior permission from the RITAM secretariat.

RITAM Secretariat will provide training/orientation on

standardized preparation of herbal remedy
method for documenting ethno-medical data
method of documenting clinical trial
method of collection and interpretation of perpheral blood smear for diagnosis of malaria.
Assist NGO in statistical design of both the treatment and prevention studies.

The duration of the project will be for two years.

Bharat

.....

ned on behalf of RITAM
O INVITATION LETTER

Signed on behalf of Samanvaya
Dr. Bharat Shah, Director

SAMANVAY
Vinoba Ashram, Gotri,
VADODARA - 390 021.

DRAFT MOU

This is the agreement between RITAM Secretariat (FRLHT) and .....NGO entered on this date of ....

Under mutual agreement THE NGO `Foundation for Revitalisation of Local health Tradition' agrees be associated with RITAM c/o FRLHT to carry out the following works in the specified time.

1) The NGO shall carry out ethno-medical survey of his locality in the villages selected for the study.

2) The NGO shall collect the ethno-medical data within 90 days of commencement of RITAM program,

3) The NGO shall submit the data to secretariat in a specified format.

4) The NGO shall engage one qualified Traditional medicine practitioner for the population study, whose salary will be paid for by RITAM.

5) The NGO shall ensure access to a Lab with a qualified Lab technician experienced in Malaria Diagnosis.

6) The NGO shall document the clinical trial data on agreed formats and provide the data to secretariat every 30 days.

7. .The NGO shall arrange for dispensing of the Standardised herbal remedies to the malaria patients of the locality for treatment & prevention of MALARIA.

8) The NGO shall participate in dissemination of positively assessed traditional practices in the locality.

9) The NGO will be entitled for a mutually agreed financial aid to support costs on RITAM.

10) The NGO will not transfer traditional information on remedies to any other commercial or research organization or individual and shall not publish any paper in a journal or Magazine without prior permission from the RITAM secretariat.

11) RITAM Secretariat will provide training/orientation on

a) standardized preparation of herbal remedy
b) method for documenting ethno-medical data
c) method of documenting clinical trial
d) method of collection and interpretation of perpheral blood smear for diagnosis of malaria.
e) .Assist NGO in statistical design of both the treatment and prevention studies.

12) The duration of the project will be for two years.

.....
Signed on behalf of RITAM

Signed on behalf of NGO 12/

NGO INVITATION LETTER

Centre for Indian Knowledge Systems
Real-world solutions from traditional science
30 (Old no. 47C) Gandhi Mandapam Road, Kotturpuram, Chennai - 600 085. INDIA.
Phone : 91-044-44710 87 / 4475862 Fax : 4471114
http://www.ciks.org e-mail : info@ciks.org

This is the agreement between RITAM Secretariat (FRLHT) and Centre for Indian Knowledge Systems, Chennai, entered on this date of .....

Under mutual agreement THE NGO 'Centre for Indian Knowledge Systems, Chennai, agrees be associated with RITAM c/o FRLHT to carry out the following works in the specified time.

1. The NGO shall carry out ethno-medical survey of its locality in the villages selected for the study.

2. The NGO shall collect the ethno-medical data with 90 days of commencement of RITAM programme.

3. The NGO shall submit the data to secretariat in a specified format.

4. The NGO shall engage one qualified Traditional medicine practioners for the population study, whose salary will be paid for by RITAM.

5. The NGO shall ensure access to a Lab with a qualified Lab technician experienced in Malaria Diagnosis.

6. The NGO shall document the clinical trial data on agreed formats and provide the data to secretariat evey 30 days.

7. The NGO shall arrange for dispensing of the Standardised herbal remedies to the malaria patients of the locality for treatment and prevention of MALARIA.

8. The NGO shall participate in dissemination of positively assessed traditional practices in the locality.

9. The NGO will be entitled for a mutually agreed financial aid to support costs on RITAM.

10. The NGO will not transfer traditional information on remedies to any other commercial or research organization or individual and shall not publish any paper in a journal or Magazine without prior permission from the RITAM secretariat.

Centre for Indian Knowledge Systems
Real-world solutions from traditional science
30 (Old no. 47C) Gandhi Mandapam Road, Kotturpuram, Chennai - 600 085. INDIA.
Phone : 91-044-44710 87 / 4475862 Fax : 4471114
http://www.ciks.org e-mail : info@ciks.org

11. RITAM Secretariat will provide training/orientation on

a) Standardized preparation of herbal remedy
b) Method for documenting ethno-medical data
c) Method of documenting clinical trial
d) Method of collection and interpretation of perpheral blood smear for diagnosis of malaria.
e) Assist NGO in statistical design of both the treatment and prevention studies.

12. The duration of the project will be for three years.

.....
Signed on behalf of RITAM

.....
Signed on behalf of NGO
A.V.Balasubramanian
Centre for Indian Knowledge
Systems, Chennai

A. V. BALASUBRAMANIAN
Director

10 Rs.



9708 16/8/2000 Rs.40/-

BRO - Jose daniel ... S/o daniel alo Raman-Nagla 6

Self

RW
R NARENDER
V L No. 42/98
R. No. 22/87-98-2001
HYDERABAD. H.P.

THIS IS THE AGREEMENT BETWEEN RITAM C/o SECRETARIAT, FOUNDATION FOR REVITALISATION OF LOCAL HEALTH TRADITION (FRLHT), NO. 50, MSH LAYOUT, ANANDNAGAR, BANGALORE AND SODARA (THE SOCIETY FOR DEVELOPMENTAL EDUCATION AND RURAL ACTION), ST. GABRIEL'S TRAINING INSTITUTE (SGTI), CHURCH COLONY, UPPAL P.O., HYDERABAD 500 039, NGO ENTERED ON THIS DAY, THE SIXTEENTH AUGUST TWO THOUSAND

Under mutual agreement, SODARA (The Society for Developmental Education and Rural Action), SGTI (St. Gabriel's Training Institute), Church Colony, Uppal P.O., Hyderabad 500 039 registered vide Reg. No. 2671 of 1988, an NGO agrees to be associated with RITAM c/o Foundation for Revitalisation of Local Health Tradition (FRLHT), No. 50, MSH Layout, Anandnagar, Bangalore to carry out the following works in the specified time.

01. The NGO shall carry out ethno-medical survey of his locality in the villages selected for the study.

02. The NGO shall collect the ethno-medical data within 90 days of commencement of RITAM program.

03. The NGO shall submit the data to Secretariat in a specified format.

04. The NGO shall engage one qualified Traditional Medicine Practitioner for the population study, whose salary will be paid for by RITAM.

05. The NGO shall ensure access to a lab with a qualified lab technician experienced in Malaria Diagnosis.

06. The NGO shall document the clinical trial data on agreed formats and provide the data to Secretariat every 30 days.

07. The NGO shall arrange for dispensing of the Standardised Herbal Remedies to the malaria patients of the locality for treatment and prevention of MALARIA.

contd.....2

10 RS.



9707 16/8/2000 Rs.10/-

BRO. JOSE DANIEL ...Br Daniel aforementioned

RUH
... No. 12/
... 29/8/...

08. The NGO shall participate in dissemination of positively assessed traditional practices in the locality.

09. The NGO will be entitled for a mutually agreed financial aid to support costs on RITAM.

10. The NGO will not transfer traditional information on remedies to any other commercial or research organization or individual and shall not publish any paper in a Journal or Magazine without prior permission from the RITAM Secretariat.

11. RITAM Secretariat will provide training/orientation on

a. Standardized preparation of herbal remedy

b. Method for documenting ethno-medical data

c. Method of documenting clinical trial

d. Method of collection and interpretation of peripheral blood smear for diagnosis of ma laria.

e. Assist NGO in statistical design of both the treatment and prevention studies.

12. The duration of the Project will be two years.

.....

.....

Signed on behalf of RITAM

(Bro. Jose Daniel)

Signed on behalf of the NGO, SODARA (The Society for Developmental Education and Rural Action), SGTI (St. Gabriel's Training Institute), Church Colony, Uppal P.O., Hyderabad - 500 039, A. P.

DRAFT MOU

Orissa Catholic Health Association

This is the agreement between RITAM Secretariat (FRLHT) and .....NGO entered on this date Local of .... 23.08.2000.

Under mutual agreement THE NGO 'Foundation for Revitalisation of Local health Tradition' agrees to associated with RITAM c/o FRLHT to carry out the following works in the specified time.

1) The NGO shall carry out ethno-medical survey of his locality in the villages selected for the study.

2) The NGO shall collect the ethno-medical data within 90 days of commencement of RITAM program,

3) The NGO shall submit the data to secretariat in a specified format.

4) The NGO shall engage one qualified Traditional medicine practitioner for the population study, whose salary will be paid for by RITAM.

5) The NGO shall ensure access to a Lab with a qualified Lab technician experienced in Malaria Diagnosis.

6) The NGO shall document the clinical trial data on agreed formats and provide the data to secretariat every 30 days.

7. .The NGO shall arrange for dispensing of the Standardised herbal remedies to the malaria patients of the locality for treatment & prevention of MALARIA.

8) The NGO shall participate in dissemination of positively assessed traditional practices in the locality.

9) The NGO will be entitled for a mutually agreed financial aid to support costs on RITAM.

10) The NGO will not transfer traditional information on remedies to any other commercial or research organization or individual and shall not publish any paper in a journal or Magazine without prior permission from the RITAM secretariat.

11) RITAM Secretariat will provide training/orientation on

a) standardized preparation of herbal remedy
b) method for documenting ethno-medical data
c) method of documenting clinical trial
d) method of collection and interpretation of perpheral blood smear for diagnosis of malaria.
e) .Assist NGO in statistical design of both the treatment and prevention studies.

12) The duration of the project will be for two years.

S. Sethi
23/08/2000

.....
Signed on behalf of RITAM

.....
Signed on behalf of NGO

NGO INVITATION LETTER

Districts selected.

Mayurbhanj) of which we will be working in
Gajapathi) any two of the districts. The exact
Sambalpur. venue of the project will be intimated later.

Thank you. S. Sethi

Catholic Health Association Of Bihar
Ursuline Convent Campus
Post Road, Ranchi 834001

is is the agreement between RITAM Secretariat (FRLHT) and... CHABI -) entered on this date of 20.08.2000.

ier mutual agreement the NGO ' Foundation for Revitalisation of Local lath Tradition ' agrees to be associated with RITAM C/o FRLHT to carry t the following works in the specified time.

The NGO shall carry out ethno-medical survey or his locality in the villages selected for the study.

The NGO shall collect the ethno-medical data within 90 days of commencement of RITAM program.

The NGO shall submit the details in a specified format.

The NGO shall engage one qualified Traditional medicine practitioner for the population study, whose salary will be paid for by RITAM

The NGO shall ensure access to a Lab with a qualified Lab technician experienced in Malaria Diagnosis

The NGO shall document the clinical trial data on agreed formats and provide the data to secretariat every 30 days.

The NGO shall arrange for dispensing of the Standardiced herbal remedise to the Malaria patients of the locality for treatment and prevention of MALARIA

The NGO shall participate in dissemination of positively assessed traditional practices in the locality

The NGO will be entitled for a mutually agreed financial aid to support costs on RITAM.

The NGO will not transfer traditional information on remedies to any other commercial or research organization or individual and shall not publish any paper in a journal or Magazine without prior permission from the RITAM secretariat.

RITAM Secretariat will provide training/orientation on

standurdized preparation of herbal remedy
method for documenting ethno-medical data
method of documenting clinical trail
method of collection and interpretation of perpheral blood smear for diagnosis of malaria
Assist NGO in statistical design of both the treatment and prevention studies

The duration of the project will be for two years.

.....
ned on behalf of RITAM

.... Director
Signed on behalf of NGO-CHABI

MOU

This is the agreement between RITAM Secretariat (FRLHT) and TRUST FOR REACHING THE UNREACHED entered on this date of 29/08/2000

Under mutual agreement THE NGO 'Foundation for Revitalisation of Local health Tradition' agrees to be associated with RITAM c/o FRLHT to carry out the following works in the specified time

1) The NGO shall carry out ethno-medical survey of his locality in the villages selected for the study.

2) The NGO shall collect the ethno-medical data within 90 days of commencement of RITAM program,

3) The NGO shall submit the data to secretariat in a specified format.

4) The NGO shall engage one qualified Traditional medicine practitioner for the population study, whose salary will be paid for by RITAM.

5) The NGO shall ensure access to a Lab with a qualified Lab technician experienced in Malaria Diagnosis.

6) The NGO shall document the clinical trial data on agreed formats and provide the data to secretariat every 30 days.

7. The NGO shall arrange for dispensing of the Standardised herbal remedies to the malaria patients of the locality for treatment & prevention of MALARIA.

8) The NGO shall participate in dissemination of positively assessed traditional practices in the locality.

9) The NGO will be entitled for a mutually agreed financial aid to support costs on RITAM.

10) The NGO will not transfer traditional information on remedies to any other commercial or research organization or individual and shall not publish any paper in a journal or Magazine without prior permission from the RITAM secretariat.

11) RITAM Secretariat will provide training/orientation on

i) standardized preparation of herbal remedy
ii) method for documenting ethno-medical data
iii) method of documenting clinical trial
iv) method of collection and interpretation of perpheral blood smear for diagnosis of malaria.
v) Assist NGO in statistical design of both the treatment and prevention studies.

12) The duration of the project will be for two years.

....

Signed on behalf of RITAM

.....

Signed on behalf of NGO

Trust For Reaching the Unreached
218, Mangaldeep Complex,
Productivity Road,
Alkapuri, Vadodara—390 007

RAYAS B - 8 , Bapu Nagar , Senthi, Chittorgarh 312 025 India
बी – 8 , बापू नगर , सेती, चित्तौड़गढ 312 025 राजस्थान प्रयास

Telefax : 01472.43788
E.mail : Prayas@ jpl.dot net.in

F. No. 345/2000

August 30, 2000

Mr. Darshan Shankar,
Director,
FRLHT,
50 MSH Layout, 2nd Stage,
3rd Main, 2nd Cross Anand Nagar,
Bangalore 560 024

Dear Darshan:

I am in receipt a copy of the minutes of the meeting held on 29th July alongwith a set about guidelines for field survey of folk practices.

As decided I am attaching a copy of the budget of three years required implementing RITAM through PRAYAS in Pratapgarh block of Chittorgarh. Please send over the revised draft MOU and other information as agreed during the meeting.

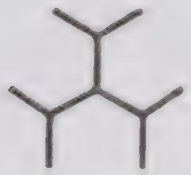
With regards.

Yours sincerely,

Narendra Gupta

Attachment: As above

Main Office : Vill. Devgarh, Dist.- Chittorgarh-312621 Tel : 01478.22900
मुख्यालय : ग्राम देवगढ़, जिला–चित्तौड़गढ़ – 312621 Fax : 01478.22828



राष्ट्रीय प्रतिरक्षाविज्ञान संस्थान

NATIONAL INSTITUTE OF IMMUNOLOGY

PROF. RANJIT ROY CHAUDHURY
D. Phil (Oxon.) FAMS., FRCP (Edin.), D. Sc. (Hon. causa)
Emeritus Scientist

Sep 2000

No.001/RRC/2000-NII /3687

September 12,2000

Fr.Sevaanand Meloo, S.J.
Foundation for Revitalisation of
Local Health Traditions,
#50 MSH Layout, 2nd Stage
3rd Main, 2nd Cross Anandnagar
Bangalore-560 024

Dear Father Meloo,

Thank you for your letter dated 5th September,2000. The Institute would require many more details before looking at the M.O.U. The Toxicology Unit does not also know what may need to be tested and if it can be fitted in. All these details are required particularly as animals are to be used. The Animal Ethics Committee has to agree to the proposal. At the moment we do not have a proposal.

With all good wishes,

Yours sincerely,

PROF.RANJIT ROY CHAUDHURY

Aruna Asaf Ali Marg, New Delhi - 110067
Tel. : 6162281, 6163009, 6103006-8, 6183004-5, ● Fax : 91-11-6162125 & 6109433
E-mail : dsprud@satyam.net.in

Sir Dorabji Tata Centre for Research in Tropical Diseases

Lt. Gen. D. Raghunath PVSM, AVSM (RETD.)
MD, DCP, FRC Path, FAMS
Principal Executive

Innovation Centre
Indian Institute of Science Campus
Bangalore - 560 012
Tel : 3460622, 3314314 (Telefax)
e-mail : sid@csic.iisc.ernet.in

SDTC/002/09/00

15 Sept 2000

My dear Dr. Shankar,

Thank you very much for your letter reference DS/Ritam/ 2000.

This centre is mandated with the task of furthering collaborative research activities aimed at developing newer drugs for the treatment of Tropical Diseases (in the broad sense) amongst other things. Hence, the type of collaboration you envisage will be quite acceptable. We can consider entering into a formal Memorandum of Understanding as and when the specifics are clear.

I hope this letter will suffice for indicating our " intent".

With regards,

Yours sincerely,

Dr. Darshan Shankar
50 MSH Layout, 2nd Stage,
3rd Main, 2nd Cross, Anandnagar,
Bangalore- 560024.

Dorabji Tata Centre for Research in Tropical Diseases

en. D. Raghunath PVSM, AVSM (RETD.)
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Innovation Centre
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SDTC/002/09/00

05 Sept 2000

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I hope this letter will suffice for indicating our " intent".

With regards,

Yours sincerely,

Dr. Darshan Shankar
50 MSH Layout, 2nd Stage,
3rd Main, 2nd Cross, Anandnagar,
Bangalore- 560024.

The draft protocol for field survey of folk practices on Malaria.

Objective:
To find out various folk practices prevalent in the community for treatment and prevention of malaria as well as for vector (mosquito) control.

Duration:
3 months.

Area of Survey:
Local area of the field work of participating NGOs

Step-1
Identify Local Healers / Traditional Practitioners / Knowledgeable house-holders (Key Informants). It is necessary to include those who are engaged in Prevention and for treatment of Malaria.

(We can also include common men and women of randomly selected households in randomly selected villages.)

Step-2

Interview the Vaidu's / Knowledgeable house-holders using the
Draft questionnaire outlined below.

STEP-3

Identify the Scientific names of the Plants
Prepare herbarium sheets of the plants
Make list of the practitioners and the remedies in a tabular form.
Make a separate list of plants / materials used in an alphabetical order

Step -4

Compile data on similar practices across the practitioners specifying the small difference if any in administration etc.

Step – 5

Make a final list of anti malarials used specifying the order of merit as per some objective criteria (including PRA).

Draft Questionnaire for Survey of Traditional Practitioner for antimalarial remedies

Centre: **Survey Sheet No:**

Personal details:

- Name of the Traditional Practitioner:
- Age: Sex:
- Address:

- Occupation: working full time for the practice? Yes / No,
  If No, Specify his occupation:

Details of Practice:

- Duration of his / her practice:
- List the type of Diseases treated by the Practitioner:
  1.
  2.
  3.
  4.
  5.

- Is the Practitioner famous for treating any one or more specific condition? Yes / No,
  If Yes, Specify vernacular name of the condition. Also specify the signs and symptoms of the condition.

No.	Vernacular name of the condition	Signs and Symptoms
1.		
2.		
3.		

- Does he / she treat fever? Yes / No,
  If yes, Please tick associated signs and symptoms the practitioner treats fever

  -High grade fever / Low grade fever
  -Fever associated with rigors
  -Fever presenting every 3rd day or every 4th day
  -Fever with enlarged liver
  -Fever with enlarged Spleen.
  -Fever with Headache / Bodyache / Vomiting / Nausea / Breathlessness / Cough / Burning Micturition / Jaundice / Otorrhoea (Ear discharge) / Unconsciousness

- Does the practitioner has any specific way to classify fever? If so, give the details

- Has the practitioner heard the term "Malaria"? Yes / No.
  If Yes, a) What is the local language term to describe this type of fever?

  b) Give details of Signs and Symptoms of Malaria the way practitioner describes:

- Does he remember any specific incident of having cured Malaria which was acknowledged by modern doctor? If Yes, Give details:

Details of Treatment Remedies:

Document the treatment procedure and drugs given by the practitioner for treatment of malaria or malaria like fevers.
(Please note that there may be more than one remedy / formulation used by the practitioner. Give exact details for each one. Please also specify the details the way practitioner differenciates different type of fever.)

Document following details about each Illness and remedy.

Illness – 1:
Describe signs and symptoms for the illness (Malaria like fevers):

Remedy / Formulation – T-1 (Used for Illness– 1) :
(Please give all the details for each component of the formulation)

1. Local name(s) of the plant
2. The time of Collection
3. The mode of collection

4. The parts collected

5. The method of preservation

6. The method of preparation (in detail)

7. The route of administration

8. Dose form (including details like with honey / water / buttermilk etc.)

9. The dose

10. The duration of the treatment

10. The contraindications pertaining to age, sex, or any other

11. The adverse effects if any.

12. The diet and other restrictions during or after the treatment.

13. The subsequent treatment methods if there is a recurrence.

Herbarium Sample:
- Please collect the herbarium sample of the plant(s). It is preferable to take the sample in the season suitable for identification (i.e. With Flowers & / or Fruits).
- It is preferable to take close-up photograph of the plant also.

(Give Similar details for more remedies for the same diagnosis in separate sheets)

Details of Preventive Remedies:

Document the remedies or drugs given by the practitioner for prevention of malaria or malaria like fevers.
(Please note that there may be more than one remedy / formulation used by the practitioner. Give exact details for each one. Please also specify the details the way practitioner differenciates different type of fever.)

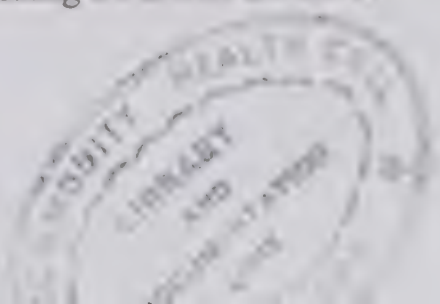
Document following details for each illness and remedy.

Illness – 1:
Describe signs and symptoms for the illness (Malaria like fevers)

Remedy / Formulation – P-1 (Used for prevention of malaria) :
(Please give all the details for each component of the formulation)

1. Local name(s) of the plant
2. The time of Collection
3. The mode of collection
4. The parts collected
5. The method of preservation
6. The method of preparation (in detail)
7. The route of administration
8. Dose form (including details like with honey / water / buttermilk etc.)
9. The dose
10. The duration of the treatment
11. The contraindications pertaining to age, sex, or any other
12. The adverse effects if any.
13. The diet and other restrictions during or after the treatment.

- What is the logic of preventive action of the drug as per the understanding of Local healers?



Herbarium Sample:
- Please collect the herbarium sample of the plant(s). It is preferable to take the sample in the season suitable for identification (i.e. with flowers & / or fruits).
- It is preferable to take close-up photograph of the plant also.

(Give Similar details for more remedies for prevention in separate sheets)

Details for Vector Controll:

What are your suggestions to keep Mosquitoes away from the home?

INFORMATIONS OF PLANTS USED

FOR THE TREATMENT OF MALARIA

1. Name & address of Participating NGO:

2. Name & address of the centre:

3. Details of the plant (plants, if compound prep.) used

Sl.No.	Botanical name(s) & Family	Local names	Parts used	Time of collection

4. Place where this plant (preparation) is used :

State(s) ..... Dt(s)..... Taluka(s)..... village(s)..... ....

5. Mode of preparation:

6. How to use, dosage, how often:

7. Restrictions , special instructions (if any):

8. Name & address of few vaidyas who use it:

9. Information furnished by (name and address):

10. Information collected by (name & address:

Date:

Signature

NB: Herbarium record attached

(use over leaf, if necessary)

ANNEXURE 1

Supplementary Sheets for remedies for Treatment of Malaria

Centre:

Survey Sheet No.
Supplement Sheet No.

Name of the Traditional Practitioner:

Age: Sex:
Address

Document following details for each illness and remedy

Illness:
Describe signs and symptoms for the illness (Malaria like fevers):

Remedy Formulation:
(Please give all the details for each component of the formulation)

1. Local name(s) of the plant
2. The time of collection
3. Mode of collection
4. Parts collected
5. The method of preservation
6. The method of preparation
7. The route of administration
8. Dose form (including details like with water /honey)
9. The dose
10. The duration of treatment
11. The contraindications pertaining to age, sex, or any other
12. The adverse effects if any
13. The diet and other restrictions during or after the treatment

-barium sample:

Please collect the herbarium sample of the plants(s). It is preferable to take the sample in the season suitable for identification (i.e. with flowers & fruits)
It is preferable to take close-up photographs of the plant also
(give similar details for more remedies for prevention in separate sheets)

What is the logic of preventive action of the drug as per the understanding of Local healers?

ANNEXURE II

Supplementary Sheets for remedies for Prevention of Malaria

Centre:

Survey Sheet No:
Supplement Sheet No.:

Name of the Traditional Practitioner:

Age: Sex:
Address:

Document following details for each illness and remedy.

Illness: Describe signs and symptoms for illness (malaria like fevers)

Remedy/Formulation (Used for prevention of malaria):
(Please give all the details for each component of the formulation)

1. Locál names(s) of the plant
2. The time of Collection
3. The mode of collection
4. The parts collected
5. The method of preservation
6. The method of preparation
7. The route of administration
8. The Dose form (including details like with honey/water etc.)
9. The dose
10. The duration of treatment
11. The contraindications pertaining to age, sex, or any other
12. The adverse effects if any
13. The diet and other restrictions during or after the treatment

Herbarium sample:

- Please collect the herbarium sample of the plants(s). It is preferable to take the sample in the season suitable for identification (i.e. with flowers & fruits)
- It is preferable to take close-up photographs of the plant also
(give similar details for more remedies for prevention in separate sheets)

What is the logic of preventive action of the drug as per the understanding of Local healers?

METHOD OF AYURVEDIC LITERATURE SEARCH

Major presenting symptom complex	**Minor symptom complex**
Fever spikes, chills, and rigors occur at regular intervals **Periodicity of fever is Tertian (once in 3 days) in P. vivax and P. ovale. It is Quartan (once in 4 days) in P. malariae. The fever is Aperiodic in P. falciparum.**	**Headache**
Fever	**Nausea, vomiting**
Splenic enlargement	
	chest pain
	Abdominal pain
	Arthralgia
	Myalgia
	Diarrhea
	Enlargement of the liver, Mild jaundice

Chart 2

TRANSLATION OF THE PRESENTATION OF MALARIA INTO AYURVEDIC TERMINOLOGIES

Most prominent symptoms	Ayurvedic equivalents
Fever with chills	Sheethapoorva jwara
Intermittent fever	Vishama vegi jwara
Rigors	Vepathu
Headache	Shirashoola
Splenomegaly	Pleehavriddhi
Chills	Romaangaharsha (goose flesh probably due to chills)
Nausea	Hrillasa
Anemia	Pandu types
Jaundice	Kamala types
Vomiting	Chhardi
Myalgia	Angamarda

Chart - 3

RESULT OF SCREENING OF TRADITIONAL ENTITIES ACCORDING TO CORRELATION HYPOTHESIS

Name of the Ayurvedic entities	*Major symptoms*	*Minor relevant symptoms*
1. Sheethapoorvaka jwara	Fever starts with chills	Head ache, Myalgia
2. Types of Vishama jwara: f) Santhatha g) Sathatha h) Anyedhyuh i) Thritheeyaka j) Chathurthaka	Intermittent fever Continuous Twice in 24 hours Once in 24 hours Once in 3 days Once in 4 days	Myalgia, heaviness
3. Vathajwara	Rigors and chills, intermittent fever, head ache	Chest pain, myalgia, constipation, abdominal pain ,
4. Sannipatha Jwara: 1.Heena pitta Vatha madhya shleshma adhika jwara	Fever with chills, Headache	Loss of appetite, Delirium, Heavy-ness
2.Heenapitta Madhya kapha Vaatha adhika jwara	Fever with rigors, Head ache	Nausea, Vomiting, loss of taste
5. Pleehodara	Splenomegaly	

Chart 4

TREATMENT PROTOCOL OF *VISHAMAJWARA* AS AN EXAMPLE

Ayurvedic Entities (Probable)	Treatment Protocol
Vishama jwara:	**General: Mridu shodhana (giving mild laxative)** **Specific: [Continuous fever] Santhatha: Decoction of Kalinga (*Holarrhena antidysenterica*), Patola patra (*Trichosanthes cucumerina*), Katurohini (*Picrorhiza kurroa*), Thritheeyaka: [Once in 3 days] Decoction of Kirathathiktha (*Andrographic paniculata* or *Swertia chirayata*), Chandana (*Santalum album*), Shunti (dried ginger – *Zingiber officinale*) Chathurthaka: [Once in 4 days] Decoction of Guduchi (*Tinospora cordifolia*), Amalaka (*Emblica officinalis*), Mustha (*Cyperus rotundus*)** **Diet:** **Gruel prepared with cold infusion of Shunti with honey, in case of associated constipation.** **Gruel prepared with Gokshura (*Tribulus terristris*), Vyaghri (*Solanum lanthocarpum* or *sometimes Solanum indicum*) in case of associated head ache.**

Toxicity Protocol

1.Acute Toxicity test.

Acute toxicity tests will be carried out on rats (only one model ...?) minimum of ten in number from each sex. The drug to be used will be given in its form of application as oral route. The effective dose will be calculated corresponding to the body weight of the animal. A lethal dose also will be predicted (how ....?) and applied in the other similar group. The drug will be administered as two doses in 24 hours and the animals will be observed as following

Toxic Signs

Severity of toxic signs.
Onset (time and mode)
Progression
Reversibility (relation to dose and time)
The animals will be observed for 7 to 14 days.

Death

The number and mode will be observed

Autopsy

All the animals will be autopsied. (dead and alive)

Histopathology

All the animal organs after autopsy will be Macroscopically observed.
In the presence of Macroscopic change Histopathological examination will be conducted.

2. Chronic toxicity Test.

One species Rodent (Rat) Model will be use for the study. (another non rodent model ..s?) Total minimum of 20 animals 10 from each sex will be used for the study in each group. The number will be increased to 15 if interim analysis required to be carried out. The TM drug will be administered in its original form through oral route for 4 weeks to three months (what's the regulation in our country ...?). The drug will be administered 7 days a week two doses a day . The administration period will be recorded.

Totally 4 groups (animals 10 >< 4 = 40) will be made.

Group –1 (Dose-a) Effective dose will be administered.

Group –2 (Dose-b) ....intermediate dose (to be calculated)

Group –3 (Dose-c) Overt Toxic dose

Group –4 Vehicle ..control group

Observations to be made and the Time of observation.

Observations	Time of Observation	Comments
General signs.: (to be defined)	Before the first dose and then daily	
Body weight	Before the first dose and then once a week	
Food and water intake	Before the first dose and then once a week	
Hematology		
TC, DC, ESR, CBC, HB% , Serum Creatinine, Blood urea, Blood sugar, S. Cholesterol. LFT etc	Before sacrifice for autopsy	
Urine	Before the first dose and then on 7 or 14 or 21st day	
Visual and Auditory test	Before the first dose and then on 7 or 14 or 21st day. Only on selected 4 animals from each group.	
Autopsy On All dead animals		1)Sacrifice all the morbid animals, don't allow to die. 2) To identify the Cause of the death & Nature of toxicity
Organ weight		
Macroscopy		
Histopathology		Histopath if macroscopically abnormal organ and tissues

EVALUTION OF IMMUNOMODULATORY PROPERTIES OF PLANT MATERIAL USED IN TRADIONAL SYSTEM OF MEDICINE FOR MALARIA

The proposed investigation is based on the current understanding of immunology indicating that immunomodulatory compounds that activate or enhance the immune response of the host, especially the cell mediated effector mechanisms, may be more effective in countering intra-cellular pathogens like malarial parasite. Plant materials used in traditional medicine will be evaluated for their immunomodulatory activity using the following experimental protocol.

1) **Selection of herbs / plant materials:**

Plant materials will be selected on the basis on their use in traditional medicine.

2) **Preparation of plant extracts:**

a) extarcts will be prepared as prescribed in the Ayurvedic/ traditional literature and practices

b) plant materials will be extracted sequentially with solvents of increasing polarity. Extracts will be dried to remove solvents and the residual material will be used for chemical finger printing and evaluation of biological activity

3) **Evaluation of immunomodulatory properties of plant extracts:**

A) In vitro assays:

Screening of the plant extracts will be carried out using the following *in vitro* assays.

Splenocytes from inbred Swiss albino mice will be treated in vitro with different concentration of plant extracts in the presence or absence of T or B cell mitogens (Con-A / LPS, respectively). Following parameters will be measured:

Lymphocyte proliferative activity will be quantitated using ^{3}H-Thymidine incorporation assay

Cytokine (IL-12, TNF-a, IL-6, IL-2, IL-4, IL-10, TGF-b etc.) will be estimated in the cultures supernatant using ELISA

Immunophenotyping using FITC/PE labelled CD-3, CD-4, CD-8, CD11c, CD-25, CD-69, CD-80, CD-83, CD-86, MHC-II, ICAM-1 will be carried out by Flowcytometry.

2) Antigen sensitized lymphocytes from the popliteal lymph nodes of inbred Swiss albino will be treated with different concentration of plant extracts in the presence of antigen.Effect on antigen specific T cell response will be measured by ^{3}H-thymidine incorporation assay. The culture supernatants will be assayed for cytokines and antigen specific antibodies using ELISA.

3) Peritoneal macrophages from inbred Swiss albino mice or monocytic cell lines will be treated in vitro with different concentrations of plant extracts in presence or absence of bacterial endotoxin. Culture supernatants will be collected after 48 hours and analysed for soluble products (TNF-α, IL-1, nitric oxide) released by macrophages.

B) In vivo models:

1) Plant extracts that show potent immunomodulatory activity in the preliminary screening will be further evaluated using in bred mice model. Mice will be fed with different doses of plant extracts for 1 - 15 days and blood samples, spleen and peritoneal macrophages will be collected at different time points.

   a) Serum samples will be analysed for cytokines (TNF-α, IFN-γ, IL-1, IL-2, IL-4, IL-6, IL-1 0, IL-12, TGF-β)

   b) Mitogenic response of spienocytes will be evaluated using ^{3}H thymidine incorporation and immunophenotyping (using FITC/PE labelled (CD4/CD8/CD25/CD69/IgG) will be carried out using Flow Cytometer.

   c) Culture supernatants from peritoneal macrophages challenged with and without bacterial endotoxin will tested for estimation of IL-12, TNF-α, IL-1, IL-6, nitric oxide.

2) Inbred Swiss albino, sensitized to specific antigen (Ovalbumin) through footpad inoculation, will be treated orally for 1-10 days with plant extracts. Popliteal lymph node cells will be removed and challenged in vitro with the antigen. Specific cellular response will be evaluated by ^{3}H thymidine incorporation and specific antibody and cytokine response will be measured in the culture supernatant by ELISA.

3) Inbred Swiss albino mice will be immunized with alum adsorbed ovalbumin and treated orally for 1-15 days with plant extracts. A booster will be given on day 15. Blood samples will be collected on days 10, 20, 30. Antigen specific antibody (IgM and IgG) response will be estimated by ELISA. IgG subclass typing will also be done.

Draft Guidelines for Clinical Trial Protocol

This are draft guidelines as details of the protocol can only be finalised after selection of the remedies.

Protocol for Selection of Traditional Remedy for Clinical Trial:

- Remedies found useful from the survey of Traditional Practitioner or literature search shall be subjected to preclinical tests (in-vivo tests for antiplasmodium effect on white mice model and immunlogical tests).
- The short-listed remedies will be subjected to 6 weeks toxicity trials.
- Selected remedies found safe shall be approved by Ethics Committee formed by RITAM secretariat before taking it for Clinical Trial on human volunteers.
- Clearance from Drug Controller of India can also be taken as per the legal requirement.

Protocol for Clinical Trials:

Objective :

To measure treatment efficacy of selected traditional remedy compared to treatment of chloroquine.

Study Design:

Randomised Clinical Trial
Masking will be preferable if practically feasible

Place of the Trial:

Clinic base trial at 5 to 6 different NGOs.

Duration of the study:

2 years.
The centers shall be reviewed at 3, 6 and 12 months to confirm adherence to study methodology.

Inclusion Criteria:

Patients clinically suggestive of Malaria and Peripheral Smear positive for P.Vivax or P. falciparum

Exclusion Criteria:

1. Patients less than 16 years and more than 60 years of age.
2. Pregnant & Lactating Woman
3. Severe Malaria: Malaria with Unconsciousness, Convulsion, Severe Anemia, Respiratory distress, Bleeding from any site, Axillary Temp. > 106* F (41.2* C)
4. Patients with any chronic debilitating condition such as Diabetes, IHD, TB, CCF.
5. History of having taken Antimalarial with in last 7 days prior to enrollment.

Termination of the study:

The study will be terminated in a subject If:

1. he developes signs of severe malaria
2. No response till the end of 5 days of treatment.

Medicine, dosage and Compliance:

Standardised dose shall be given to each patient.
Dose will be determined considering the results of field survey, literature search, experience of the experts and toxicity trials.
Check on compliance by having look at the remaining amount of the given dose.

Method of documentation:

The documentation proforma will be provided by the RITAM secretariat which will include:
-Patient Profile
-Sickness History
-Clinical Findings
-Laboratory Investigations
-Treatment and dose given
-Details of Compliance
-Follow up and Outcome

Lab. Investigations to be carried out will include Peripheral Smear for Malarial Parasite on day 0, 3, 7, 14, 28.
LFT / RFT required? If so, frequency?

N.B: A separate case sheet will be maintained by ISM practitioner with their own parameters of assessment (to be developed by Committee of ISM experts)

Interim Analysis:

- Interim analysis will be done at the end of first, third and sixth month.
- It will analyse the relevance of the study and decision to be taken to continue, modify or stop the study as recommended.

TREATMEN T RECORD PART I

1. Address of the Hospital/Health Centre

2. Patient profile:
Name: Age: Date:
Sex:

Address.

3. History of the ailment:

	SYMPTOMS						SIGNS			LA B R E POR T			
4. Diagnosis Mark (✓) if yes " (X) if no	Fever	Chill	Sweat	Head ache	Body ache	Vomiting	Enlarged liver	Enlarged spleen	Anae-mia	Plasmodium		Hemog lobin	Any other
										Vivax	Falci-parum		
5. Improvement: 1 - 3 days													
3 - 6 days													
6 - 10 days													

6. Follow up steps taken, if needed :

7. Treated by

(Please attach the relevant informations about investigation to the record sheet)

(RITAM, C/o FRLHT, No. 50 MSH Layout, 2nd State, 3rd Main, Anandnagar, Bangalore -- 560 024, ☎ 3336909,3330348, fax 3334167)

Clinical Evaluation of Herbal Remedies and Medicinal Plants

{Taken from the Draft – Consultative Document on Ethical Guidelines on Biomedical Research involving Human Subjects – Indian Council of Medical Research, New Delhi 1997 (Not to be quoted).}

The guidelines given below relate to herbal remedies and medicinal plants which are to be clinically evaluated for use in the allopathic system of medicine and which will be used in allopathic hospitals. The evaluation also will be carried out in allopathic hospitals and the registration of the plant extract or compound will follow the procedure laid down by the office of the Drugs Controller General of India for allopathic drugs. This does not pertain to guidelines for ayurvedic drugs or unani drugs to be clinically evaluated by experts in those systems of medicine to be eventually used by ayurvedic and unani physicians in their own hospitals and clinics.

All the general principles of clinical trials described earlier pertain also to herbal remedies. However, there are special features regarding herbal remedies which need to be kept in mind during their clinical evaluation.

The first feature is that at te time of clinical evaluation, a lot may be known about the plant or its extract. There could be extensive literature about use of this ancient Ayurvedic or Unani literature and other organised systems or , indeed, the plant may actually be in use by physicians of the traditional systems of medicine for a number of years. The substance to be clinically evaluated will be used as is being used now or as has been described in the texts.

The second consideration is that it is possible that clinical evaluation of a plant extract or a compound isolated from an extract has to be carried out which has never been in use before and has not ever been mentioned in ancient literature.

The guidelines for these two types of substances cannot be the same and therefore, given below are specific guidelines for substances which could fall into either group.

A. For plants and herbal remedies currently in use or mentioned in literature of any organised system of medicine.

It is important that the herbal preparation to be clinically evaluated has been described in an authentic and recognised text of the particular system of medicine and prepared strictly in the same way, incorporating GMP norms or standardization as far as possible. It may not be necessary to undertake phase I studies. No toxicity study may be needed for phase II trial unless there are reports suggesting toxicity or the use is to be for more than 3 months. It should be necessary to undertake 2-4 weeks toxicity study in 2 species of animals in the circumstances pointed out in the preceding sentence or when a larger multicentric phase II trail is subsequently planned based on results of phase II study.

Clinical trials with herbal preparations should be carried out only after they have been standardized and markers identified to ensure that the substances being evaluated are always the same. The recommendations made earlier regarding informed consent, inducements for participation, information to be provided to the subject, withdrawal from study and research involving children or persons not in full control of their senses all apply to these trials. These trials have also got to be approved by the appropriate scientific and ethical committees of the concerned institutes.

There is one special aspect which needs to be emphasised. Since the substance to be tested is already in use in the Ayurvedic or Unani system of medicine or has been mentioned in these texts, toxicity testing in animals has been considerably reduced. However, it is essential that such clinical trials are carried out only when a competant ayurvedic or unani physician is co-investigator in this clinical trial and the clinical evaluation is carried out jointly by the allopathic physician and the specialist from the traditional system of medicine. It would not be ethically acceptable nor morally justifiable, if an allopathic physician, based on references in ayurvedic literature, carries out clinical evaluation of the plant without any concept or training in Ayurveda or the Unani System of medicine – hence the necessity for association of a specialist from these systems of medicine.

B. **For new plants and extracts <u>not</u> in use or mentioned in literature.**

The other situation would be when an extract of a plant or a compound isolated from the plant has to be clinically evaluated for its therapeutic effect. This is, for all purposes, a new substance never been tested before. All the acute, subacute and chronic toxicity tests which need to be carried out with any new synthetic compound would need to be carried out with this preparation before clinical evaluation.

When the toxicity tests have been completed, and there is no evidence of undue toxicity a decision has to be taken whether the substance should be clinically evaluated. If the decision is made to carry out a clinical evaluation, this has to be carried out by a physician of the modern system of medicine i.e. allopathy. There is no need nor necessity to have a specialist in the traditional systems of medicine involved as a co-investigator in these trials as this is not an ayurvedic or unani drug and, in its present form, has not been used in the traditional systems of medicine. It should be tested just as any new synthetic drug would be tested and all the observations made earlier would also apply to this compound or extract.

India's Medical Heritage

A New Awakening



Foundation for Revitalisation of Local Health Traditions

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India's Rich Medical Heritage

India has one of the world's most sophisticated indigenous medical cultures, with an unbroken tradition coming down across more than four millennia. Though this medical heritage is many centuries old, even today millions of people, in villages, towns and cities across the country, depend upon it for their health care needs. This living medical tradition encompasses two streams — folk medicine and codified medicine.

Folk medicine includes the diverse practices followed by nearly 5,000 ethnic communities across the country. Millions of households practise home remedies, the recipes and formulae for which have been handed down orally from generation to generation. Traditional birth attendants manage 90% of rural deliveries. It is also estimated that traditional bonesetters handle 60% of orthopaedic cases in the country. Over a million folk healers in different areas attend to specific health needs of the local population. Their skills range from treating common ailments to conditions like hepatitis, *visha* (poisons) and mental diseases.

Though these traditions are empirical in nature, over 200 million people in rural India, with limited access to organised health services, depend to varying degrees on the folk tradition for their medical needs.

Codified medical systems include Ayurveda, Siddha, Tibetan and Unani systems of medicine, with sophisticated theoretical foundations. The vast knowledge in

The Codified Traditions

Ayurveda: A science of life that has served Indians since Vedic times. It defines health as a state of equilibrium of the physiological, sensory, mental, and spiritual being.

Siddha: A regional manifestation of Ayurveda with specialisation in accupressure (*varman*), pulse diagnosis (*nadi pariksha*), and drug formulations which use metals and minerals, apart from plants.

Tibetan (*Amchi*): A regional manifestation of Ayurveda, this system spread with Buddhism to the trans-Himalayas. As per this system, a person is considered to be in a healthy state, i.e. "swasthya", when he is established in himself or is one with nature.

Unani: Originating in Greece, this system was popularised in India during the 14th century by Muslim rulers. It is based on the balance of four humours in a healthy body, i.e., *dam* (blood), *balgham* (phlegm), *safra* (yellow bile) and *sanda* (black bile), and diagnoses a disease through *nabz* (pulse), *baul* (urine) and *baraz* (stool).

the codified traditions has been documented in tens of thousands of medical manuscripts. It is not commonly known that these systems cover all basic aspects and branches of medicine, from general medicine to specialised fields like paediatrics, psychiatry, ENT, ophthalmology and surgery. They even cover plant and veterinary medicine (*vrksh* and *pashu* ayurveda). Despite several constraints, these codified medical systems are alive and are gradually regaining lost ground. Currently, there are over 6,00,000 licensed traditional medical physicians in India.

Both these medical streams are closely allied with nature. They use over 8,000 species of medicinal plants, trees, shrubs, grasses, tubers, climbers, and even lower plants like lichens and orchids. They also know the medicinal uses of over a hundred species of animals, birds, fish and insects, and several metals and minerals.

A Great Tradition Under Threat

Due to the rapid degradation and loss of natural habitats juxtaposed with the overharvesting of some species, the biological wealth that is so intrinsically important to these systems of medicine is being destroyed or becoming endangered. Over 200 species of medicinal plants are already on the RED list.

Folk healers (*nattu vaidyas*) cater selflessly to the various primary health care needs of the communities they live in. They even treat conditions like mental diseases and *visha* (poisons). There are also opthalmologists, who can treat degenerative eye diseases with herbs.

Most of these folk healers have alternative professions from which they earn theirlivelihood. Legend has it that should they use their knowledge to exploit others, they stand to lose their powers.



A nattu vaidya preparing medicines (left), and treating a patient for snakebite (right)

The knowledge base and practice of both the folk and codified streams have during the last century, become marginalised due to political, social and economic reasons. Despite their widespread existence during the last fifty years, no systematic national survey has been carried out after Independence to assess their contribution to public health. To date, no appropriate research models exist which are designed to do a fair assessment of their achievments, and public investment for their revitalisation is negligible.

The Situation Today

Under the influence of colonialism, the political and social leadership in India had, for some time, developed a disregard for their own indigenous cultural intellectual and spiritual traditions. It is only in recent years that a new awakening is prompting another look into the Indian medical traditions. Paradoxically, this discovery is also being inspired to some extent by the urgent search in the west for "alternatives" to complement the mainstream medical systems.

A serious national effort and substantial investments are called for in order to demonstrate the contemporary relevance of both the folk and codified streams of our medical heritage, so that their benefits and fuller potential can be made more widely available to the Indian public and to the world at large.

If urgent action in this direction is not taken immediately, we are in danger of irretrievably losing our heritage.

FRLHT: Its Genesis

The Foundation for Revitalisation of Local Health Traditions (FRLHT) was founded as an independent, non-governmental society in October 1991 (registered under the Societies Registration Act 1890, Maharashtra - Reg. No. 674/1991/G.B.B.S.D., dated 23/10/1991). The idea of FRLHT grew out of a grassroots non-government movement, which started in 1986, for revitalising India's rich and diverse health cultures.

FRLHT's concern to "revitalise" local health traditions should not be mistaken as an attempt to revert to the past; rather, it is an attempt to discover the contemporary relevance of our widespread traditions in order to serve the country's present and future health care needs. If modernisation is not understood to mean "westernisation", FRLHT's efforts may be seen to be an attempt to modernise our health traditions from their own roots.

FRLHT holds the view that revitalisation of folk traditions holds a real potential for self-reliance for millions of rural people in primary health care. As for the codified systems, their strengths in specialised fields like diagnostics and drug development, and in medical areas like immunology, orthopaedics, ophthalmology, mental health, muscular and nervous disorders, cardiac and respiratory ailments, mother and child care, and food and nutrition, can be built upon to make new and original contributions to public health in India, and to the world of medicine.

The Mission

FRLHT has embarked on a mission to revitalise India's medical heritage. This task involves conserving its resource base of plants, animals and minerals, demonstrating contemporary applications of its knowledge base, and energising its social traditions. This is so large and multi-faceted a task that a single organisation can only undertake "pilot demonstration projects", support strategic research in key areas and promote networking. This is the role that FRLHT has chosen to fulfil its mission.

FRLHT works through its links with serious practitioners and scholars of the traditional medical community, modern physicians and scientists, community health organisations, conservationists, industry, government and international organisations.

Thrust Areas

To fulfill its mission, FRLHT focuses its efforts in specific areas:

- Conservation research and sustainable utilisation of the bio-diversity used by traditional medicine
- Computerised multi-disciplinary databases on medicinal plants
- Role of traditional medicine and primary health care

- Strategic research on selected medical and sociological aspects of traditional systems of medicine
- Fundamental research on the theoretical foundations and epistemology of traditional medicine
- International cooperation and networking in the fields of conservation and traditional medicine

Organisational Resources

FRLHT's office is located in Bangalore. The office is well-equipped, and staffed by a core team of senior foresters, botanists, computer professionals, traditional physicians and young researchers. A 15-acre site, 20 km from Bangalore, has been offered by the Government of Karnataka for establishing a medicinal plants garden and a national herbarium.

The highest policy-making body of the Foundation is the Governing Council It consists of eminent figures from a wide spectrum of public life, including a representative of the Ministry of Environment & Forests, Government of India.

The day-to-day operations of FRLHT are overseen by the Executive Board. The Board is responsible for formulation of new projects, raising financial resources and designing suitable management systems for the working of the Foundation. The organisation is headed by an Executive Director supported by a core team of professional staff. Large projects within FRLHT are managed by Project Management Boards, specially constituted for the duration of the projects.



The FRLHT office at Bangalore

FRLHT At Work

Since 1993, FRLHT has initiated a pioneering collaborative programme in response to the crisis of dwindling medicinal plant resources.

FRLHT, in collaboration with the State Forest Departments, local NGOs and research institutes, has established a chain of conservation sites in the Western and Eastern Ghats, across the states of Kerala, Tamil Nadu, Karnataka, Andhra Pradesh and Maharashtra.

This network is called the "Medicinal Plant Conservation Network" (MPCN). It is a major step towards the conservation of wild genetic resources — the first of its kind in India. The MPCN is today conserving about 1,400 species of medicinal plants, including 70 RED-listed species.

The Medicinal Plants Conservation Network (MPCN)

The MPCN has adopted a two-pronged strategy. On one hand, there are forest reserves, where wild populations of medicinal plants are conserved in their natural habitats, so that they can freely breed, evolve and multiply. This ensures their long term survival. About 50 Medicinal Plants Conservation Areas have been set up in cooperation with the State Forest Departments to conserve the medicinal plants diversity in a range of vegetation types and ecosystems.



A woman tending her herbal garden at home

On the other hand, medicinal plants, especially the threatened species, are being conserved in ethnomedicinal gardens. Fifteen ethno-medicinal conservation parks have been established in collaboration with NGOs and research institutes to conserve plants known and used by various ethnic communities of Southern India.

In the MPCN network, local communities are being motivated to form management and protection committees to secure long term conservation of forest reserves, and they are also being encouraged to revitalise their local health traditions. A Green Health Programme has been launched to encourage rural households to grow and use medicinal plants for primary health care. Training programmes and material have been developed on conservation and utilisation of medicinal plants. These programmes are offered to NGOs, foresters and community leaders.

Small enterprises related to growing medicinal plants and value-addition are being promoted in rural communities as an integral part of the conservation strategy. These units demonstrate how the local communities that live around the natural habitats of the medicinal plants can economically benefit from conservation projects.

A chain of nurseries and seed banks have been established around the conservation sites to provide basic planting material to non-commercial as well as commercial user groups. This nursery network raises about 600 species and is spread across different agro-climatic regions.

geneNet, an informal newsletter, is the voice of the MPCN. It gives information on the conservation activities of the MPCN and establishes links with the end-users of medicinal plants, who are the ultimate clients of the MPCN.

FRLHT has a wealth of research data collected during the course of its activities. The Medicinal Plants Conservation Research, Herbarium & Database Unit has developed a multi-disciplinary, computerised medicinal plants database, which is constantly expanding and being updated. The main objective of the database is to generate reliable multi-disciplinary information on the identity, distribution, threat and conservation status, trade data and agro-technology of medicinal plants. This will serve the information needs of sectors like forestry, conservation science, agriculture, drugs and cosmetics, and trade.

Medicinal Plants Conservation Research, Herbarium & Database Unit

The FRLHT biocultural herbarium houses, and maintains records of over 12,000 voucher specimens relating to approximately 2,300 wild plants of Southern India, both medicinal and non-medicinal. Around 1,500 of these are known medicinal plants, with the remaining holding promise of untapped potential. These medicinal plants occur in different forest types of Southern India, viz., tropical evergreen, tropical semi-evergreen, tropical moist deciduous, etc. The herbarium also keeps raw drug samples of medicinal plants used in trade.

FRLHT has made a pioneering effort to assess the rare, endangered and threatened medicinal plants of Southern India, based on guidelines prepared by the International Union for Conservation of Nature. To focus conservation action on these threatened species, a *Red Data Book* of medicinal plants is being prepared.

This information would help promote the conservation of these species, facilitate their propagation and cultivation, and ultimately reduce the pressure of their exploitation in the wild that could result in their extinction.

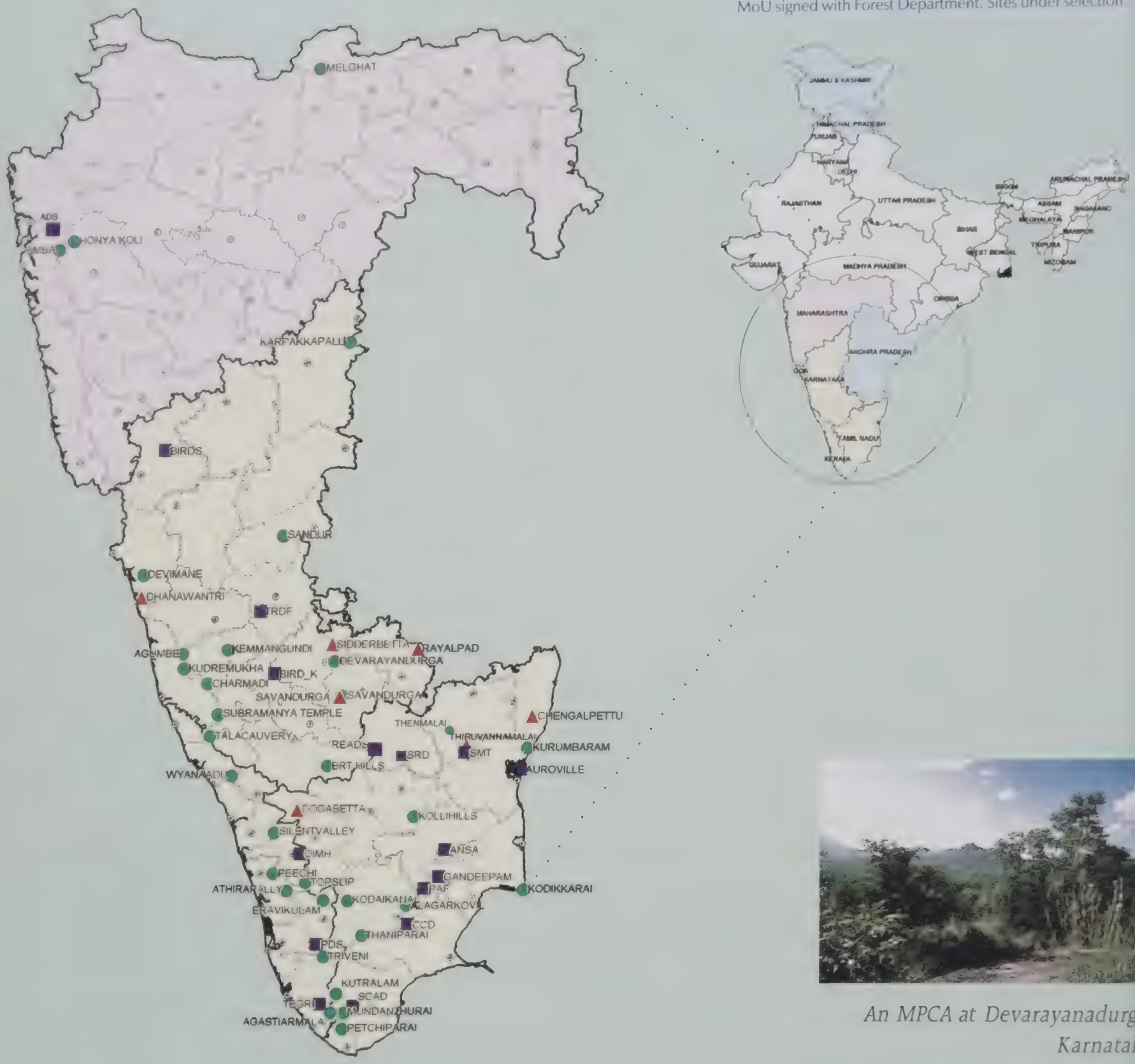


Voucher specimen of Cassia tora

The Unit has also initiated the preparation of eco-distribution maps of about 300 of the most threatened plants of Southern India, with their precise latitudinal and longitudinal locations. The distribution patterns of these prioritised plants are analysed based on geographical data.

Research into the techniques of plant propagation and cultivation of selected medicinal species has been undertaken.

FRLHT's Operations In India



The Medicinal Plants Conservation Network

- Medicinal Plants Conservation Area (MPCA)
- Medicinal Plants Conservation Park (MPCP)
- Medicinal Plants Development Area (MPDA)

An MPCA at Devarayanadurga, Karnataka



A conservation site at Agastiar, Kerala

Traditional Indian Systems of Medicine Research & Informatics Unit

This Unit is designed to serve the needs of medical researchers, community health organisations and industry by providing them specialised data related to the traditional knowledge about plants.

FRLHT is conducting a study to compile a list relating the ethnic names of medicinal plants used in the oral traditions to their botanical names. As of today, botanical names of over 6,000 medicinal plant species can be accessed in Sanskrit, Marathi, Hindi, Kannada, Tamil and Malayalam.

Coscinium fenestratum

The IUCN terms rare and endangered species of plants as "RED-listed" species. In cooperation with the State Forest Departments, FRLHT has been making efforts to identify forest areas where there are still populations of such species.

One such example is Coscinium fenestratum. A Medicinal Plants Conservation Area (MPCA) has been established in an area in Idukki District in Kerala, which has been identified for conserving wild populations of this RED-listed species.



A comprehensive referenced database of the medicinal plants of India, used in different codified systems — Ayurveda, Siddha, Tibetan and Unani — and folk systems is under preparation. A database and expert system on the *materia medica*, containing referenced information about the processes and formulations of traditional Indian Systems of Medicine, is also being developed.

Documentation and rapid assessment of living local health traditions in Southern India is under way.

Communication & Education Materials Development Unit

Recognising that the success of its initiatives depends on active support from the public at large, FRLHT has set up a Communication and Education Materials Development Unit.

This Unit coordinates activities to create public awareness for the conservation and sustainable use of medicinal plants. Efforts are directed towards relevant audiences through appropriate media. These include the bimonthly magazine *Amruth*, India's only magazine on medicinal plants, newsletters like *geneNet* books, films, puppet shows, exhibitions, posters and manuals. The publications and other communication material produced by FRLHT are listed in Appendix A.

Through its Education Interaction Programmes, nature camps and exhibitions are organised for school children, where the uses as well as the importance of



A puppet show on the use of medicinal plants in child care

conserving medicinal plants are emphasised. The media used include puppet shows, *yakshaganas*, video films, posters and appropriate publications. Signages are being developed, for use at conservation sites, for creating greater awareness about the biodiversity and cultural diversity related to medicinal plants.

The Unit is also working to promote public awareness about the relevance of folk medicine. District and state conventions for *nattu vaidyas* (folk healers) have been organised, where outstanding individual contributions of folk healers are recognised and rewarded, and where they are motivated to pass on their traditional wisdom to the younger generation.



A nattu vaidya shares his knowledge at a convention

In urban areas, too, awareness campaigns on the use and importance of medicinal plants have been organised, targeted at schools and households. Herbal gardens have been set up in schools with the active participation of the students.



Getting the message across: housewives and schoolchildren learn about medicinal plants and their uses



Through workshops conducted by a team of Ayurvedic doctors, groups of women have been introduced to medicinal plants which are useful in treating common ailments.

Future Plans

Medicinal Plants Conservation Network (MPCN)

In the years to come, FRLHT intends to grow into a competent knowledge-based institution servicing a network of Indian organisations engaged in the conservation and sustainable utilisation of medicinal plants, who in turn provide useful services to various non-commercial and commercial end users of medicinal plants.

It intends to promote conservation activities in other states in India, in different agro-climatic regions, the immediate priority being the Western and Eastern Ghats and the northwestern Himalayas.

It expects to establish a nationwide network of medicinal plants nurseries, and will also promote community-based micro-enterprise to involve rural communities more actively in conservation.

Medicinal Plants Conservation Research, Herbarium & Database Unit

FRLHT will pursue its efforts to make the Medicinal Plants Conservation Research, Herbarium & Database Unit a reliable certification and reference centre for botanical and cultural information on the medicinal plants of India. The database is expected to evolve into a valuable source of information on their conservation status, nursery techniques, medicinal uses and trade. More raw drug samples of the *officinalis* parts of medicinal plants will be added to the herbarium, and a pharmacognostic unit will be set up.

Traditional Medicine and Primary Health Care

FRLHT will work towards putting life back into the melting pot of cultural diversity and biodiversity represented by local health traditions.

FRLHT will set up a network of regional training centres for community health workers of the government and non-government sectors, where they could learn the practical applications of using medicinal plants for primary health care. These would complement and supplement programmes aimed at achieving "health for all".

Research on Sociological, Medical and Epistemological Aspects of Traditional Systems of Medicine

FRLHT intends to explore the contemporary relevance of Indian medical traditions by participating in collaborative projects on health problems of local, national or global concern in fields like obstetrics, mental health, orthopaedics, ophthalmology, immunology, muscular and nervous disorders, and geriatrics, and public health areas like malaria control. Research will also be undertaken to assess the contempory relevance of the oral health cultures in rural India.

The subjects for all these studies will be strategically selected and implemented with competent collaborators, so that they can lead to Traditional Medicine-oriented changes in public health policies.

FRLHT will also promote fundamental research on the epistemology of traditional Indian Systems of Medicine — their foundations, schemes of internal logic, principles, concepts and categories — so as to promote a proper understanding of the indigenous Indian medical knowledge systems.

There is also a plan to establish clinical research facilities in the form of a Rasayan and Panch Karma Research Centre in Bangalore.

International Cooperation

FRLHT intends to explore mutually beneficial South-South collaborative projects with other countries in Asia, Africa and Latin America that have a rich medical heritage of their own. The operational framework of various traditional health cultures may share some common ground with regard to foundations, concepts, categories & natural resources, and these projects will explore areas like conservation of medicinal plants, natural products databases, drug development, management of tropical health conditions and comparative epistemology.



An International Conference organised by FRLHT at Bangalore in February 1998

FRLHT is a founding member of an international network called **GIFTS of Health** (Global Initiative For Traditional Systems of Health) based in the Oxford University, U K, and the Executive Director of FRLHT is a member of its Executive Board.

Research Fellowships

FRLHT plans to raise an endowment to award fellowships for the documentation of special medical achievements of traditional Indian Systems of Medicine, conservation biology related to medicinal plants, and literary research on medicinal plants from medical manuscripts. Gurukul apprenticeships for medical students with outstanding traditional physicians will also be promoted via these scholarships.

What FRLHT Can Do For You



An MPCN nursery

Planting Materials

× Provide information on the sources of planting materials from the MPCN nurseries to meet specific requirements of user groups like rural and urban households, *nattu vaidyas*, traditional physicians (of Ayurveda, Siddha, Tibetan and Unani systems of medicine) industry and institutions (NGOs, schools, colleges, factories, clinics, hospitals, etc.)

Information

× Provide information on the propagation techniques of medicinal plants, for personal or commercial use

× Provide reliable educational material pertaining to the conservation and sustainable utilisation of medicinal plants (refer Appendix A for the list of books and publications produced by FRLHT)

× Provide information on the botanical identification, conservation status, and trade information of medicinal plants from its databases and herbarium. This information could be useful to foresters, agriculturists, conservationists, and for those in industry (pharmaceuticals/cosmetics/food), trade, and community health

× Provide specialised information from the *materia medica* of codified Indian medical systems

Training & Education Material

× Design and organise training packages on various aspects of conservation, primary health care and community-based enterprises

× Design and organise advanced training (including international courses) on medicinal plants conservation, traditional Indian Systems of Medicine and public health; on industrial applications of the *materia medica* of Indian Systems of Medicine; and on the epistemology of Ayurveda

× Produce educational material and communication aids on various facets of traditional systems of medicine in different media



A training session on medicinal plants

Consultancy Services

× Provide consultancy services on specific aspects of medicinal plants conservation and plant-based applications of traditional systems of medicine

— in undertaking research on threat status, trade, distribution and inventories

— in the evaluation of projects

— in studies related to choice of species for cultivation in particular habitats

— in literature research from traditional medical texts

— in the selection of herbal formulations for industrial production



An in situ site at Thaniparai, Tamil Nadu

— in the design of large scale medicinal plants conservation projects

— in the design of projects for Traditional Medicine and primary health care

— in the design of medicinal plant databases.

Appendices

FRLHT produces books, magazines, videos, posters and other material with information on medicinal plants and their uses. These are available at the FRLHT office in Bangalore, and can be ordered through the mail. Please contact the Medplan Conservatory Society, 8 MSH Layout, 1st Floor, 4th Main, Anandnagar, Bangalore 560 024, for details about how you can order these publications and collateral material.

In the list below, prices indicated are exclusive of postage and packing. All literature, posters, stickers and schoolbook labels are available in English, Kannada, Malayalam and Tamil unless otherwise specified.

Appendix A
List of Publications & Collateral Material

Title	*Price (Rs.)*
1. A User's Guide to Medicinal Plants for Primary Health Care	50/-
2. How to Grow Medicinal Plants	35/-
3. Neem	30/-
4. Rare, Endangered and Threatened Medicinal Plants Poster	15/-
5. Green Health Poster # 3	
Kannada, Malayalam, Tamil	40/-
English	45/-
6. Stickers on Rare, Endangered and Threatened Medicinal Plants of Southern India (Set of 10)	
Price of full set	20/-
Price of each sticker	2/-
7. Booklets on medicinal plants and revitalisation of local health traditions (Set of 9, only in Tamil)	
Price of full set	135/-
Price of each booklet	15/-
8. Schoolbook labels with RED-listed medicinal plants (1 sheet of 16 multi-coloured gummed labels)	5/-
9. Jute Bags (available with either of 2 messages in English: *Medicinal Plants For Survival* or *Save Medicinal Plants*	75/-
10. White Cotton T-shirts with Medicinal Plants Prints (Available in 2 sizes: Medium, Small)	75/-
11. "Green Health": video on using medicinal plants in primary health care	500
12. "Green Healers": video on folk health practitioners	500

Title		*Price (Rs.)*
13. Plants in Ayurveda: A Compendium of Botanical and Sanskrit Names of Plants	(Only in English)	800/-
14. AMRUTH: Magazine on medicinal plants, published bimonthly		
(Only in English)		
For Individuals		
1-Year Subscription		150/-
3-Year Subscription		400/-
12-Year Subscription		1,500/-
For Institutions		
1-Year Subscription		250/-
3-Year Subscription		600/-
12-Year Subscription		2,500/-
15. geneNet: The quarterly MPCN newsletter		
(Currently in English; soon in Kannada, Malayalam, Tamil)		
1-Year Subscription		100/-
3-Year Subscription		280/-
5-Year Subscription		450/-

Appendix B Glossary

Conservation biology	The science of conservation of life and living organisms
Epistemology	Branch of philosophy that enquires about the sources of human knowledge, its possible limits, and to what extent they can be certain or only probable
Materia medica	(Latin) Materials used in medication
Officinalis	Used in preparing medicine
Panch Karma	In Ayurveda, five therapeutic procedures for internal cleansing of the body
Pharmacognosy	The study of identification of raw drugs
Rasayan	Drugs that facilitate rejuvenation of the body
Yakshagana	A folk theatre form of Karnataka

FRLHT Governing Council

Mr Sam Pitroda	*Former Advisor to the Prime Minister of India*	Chairman
Mr P R Krishnakumar	*MD, Arya Vaidya Pharmacy, Coimbatore*	Member
Representative of Secretary	*Ministry of Environment & Forests, Govt of India*	Member
Dr P Pushpangadan	*Director, TBGRI, Thiruvananthapuram*	Member
Dr S S Badrinath	*Director, Shankar Netralaya, Chennai*	Member
Vd G G Gangadharan	*Director, CIMH, Coimbatore*	Member
Dr Ashok Jhunjhunwala	*Professor, IIT, Chennai*	Member
Mr A V Balasubramaniam	*Director, CIKS, Chennai*	Member
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Vd R M Nanal	*Ayurveda Physician, Mumbai*	Member
Dr Gerard Bodekar	*Chairman, GIFTS, Oxford, UK*	Member
Dr Prakash Desai	*Chief of Staff, West Side Medical Centre, Chicago, USA*	Member
Dr M S Valiathan	*Vice Chancellor, Manipal University, Manipal*	Member
Vd Bhagwan Dash	*Ayurveda Physician, New Delhi*	Member
Prof Sukhdev	*Emeritus Scientist, New Delhi*	Member
Dr Ranjit Roy Chaudhury	*Emeritus Scientist, New Delhi*	Member
Mr S Varadachary	*Retired Civil Servant, Chennai*	Member
Mr Darshan Shankar	*Executive Director, FRLHT, Bangalore*	Member
Mr D K Ved	*Coordinator, Research, FRLHT, Bangalore*	Member

To know more about FRLHT and how it can help you, or how you can participate in its activities, contact the persons/departments specified below:

Head, Consultancy Group

For consultancy services offered by FRLHT

The MPCN Secretariat

For general information on MPCN

Information on MPCN nurseries

Collaborative projects with MPCN members

The Head, Medicinal Plants Conservation Research & Database Unit

For herbarium related services

Databases on distribution, trade, agro-technology

The Head, Traditional Medicine Research & Informatics Unit

For specialised databases on traditional medicine

The Medplan Conservatory Society

(8 MSH Layout, 1st Floor, 4th Main, Anandnagar,

Bangalore 560 024. Phone: (91 80) 343 4464)

For subscriptions to **Amruth,** *India's only magazine on medicinal plants*

Books, other publications and films

Education material

Exhibitions

Setting up herbal gardens in educational institutions, homes and organisations

Foundation for Revitalisation of Local Health Traditions
50 MSH Layout, 3rd Main, 2nd Stage, Anandnagar, Bangalore 560 024.
Phone: (91 80) 333 6909, 343 4465. Fax: (91 80) 333 4167. Email: root@frlht.ernet.in



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